Can RAPID3, an Index Without Formal Joint Counts or Laboratory Tests, Serve to Guide Rheumatologists in Tight Control of Rheumatoid Arthritis in Usual Clinical Care?

Theodore Pincus, M.D.

Abstract
Tight control of rheumatoid arthritis (RA) may be guided by RAPID3 (routine assessment of patient index data), an index without formal joint counts or laboratory tests, which can be scored on a multidimensional health assessment questionnaire (MDHAQ) in 5 seconds, compared to 42 seconds to score a standard HAQ, 90 seconds to perform a 28-joint count, 114 seconds to score a disease activity score 28 (DAS28), and 106 seconds to score a clinical disease activity index (CDAI). RAPID3 scores are correlated significantly with DAS28 and CDAI (rho > 0.65, p < 0.001), and distinguish active from control treatment similarly to DAS28 and CDAI in clinical trials of methotrexate, leflunomide, adalimumab, abatacept, certolizumab, and infliximab. RAPID3 scores can be used to classify patient disease activity status as high (> 12), moderate (6.1-12), low (3.1-6), and remission (≤ 3), analogous to activity categories of DAS28 and CDAI. In clinical care settings, 78% to 84% of patients who met the criteria for moderate-high activity status of greater than 3.2 for DAS28 and greater than 10 for CDAI had RAPID3 scores greater than 6, while 68% to 77% who met low activity-remission criteria of a DAS less than or equal to 3.2 and a CDAI of less than or equal to 10 also had RAPID3 scores that were less than or equal to 6. The most effective strategy to collect MDHAQ-RAPID3 data is for the receptionist to ask each patient to complete a questionnaire upon registration at each visit, prior to seeing the physician in the infrastructure of clinical care. Clinical judgment ultimately enters into all clinical decisions, but judgment is enhanced considerably by quantitative data provided by the MDHAQ and RAPID3 to supplement nonquantitative impressions. RAPID3 provides a feasible, informative quantitative index for busy clinical settings.

This essay presents a rationale for any rheumatologist to administer an MDHAQ (multidimensional health assessment questionnaire) to score a RAPID3 (routine assessment of patient index data), an index without formal joint counts, at each patient visit in usual care. The MDHAQ provides valuable information for all visits, including RAPID3 scores, to help guide tight control of rheumatoid arthritis (RA), as well as other rheumatic diseases. Clinical judgment ultimately enters into all clinical decisions, but judgment is enhanced considerably by quantitative data.

A. What Is the Rationale for Tight Control of Rheumatoid Arthritis, Guided by Quantitative Measurement?
Traditional therapy for RA, until the 1990s, was based on a “go low, go slow” approach, with directives to use disease-modifying antirheumatic drugs (DMARDs) only after joint damage was seen.1 DMARDs were often termed “remission-inducing,” primarily on the basis of the results of short-term clinical trials. However, sustained remission over more than 2 years was seen in fewer than 2% of patients.2 Furthermore, the most prominent DMARDs until the 1990s, gold salts and penicillamine, were used only after establishing certainty of a diagnosis of RA, primarily because of potential severe, unexpected adverse events, including fatal outcomes.

One source of underestimation of the severity of RA until the 1980s, in addition to clinical trial results, was incorrect interpretation of data from population-based studies in which more than 50% of people who met classification criteria for RA had no evidence of disease 5 years later.3 It was thought...
that this phenomenon applied to patients with RA seen in clinical settings. However, only 25% of people who met RA classification criteria in studies of entire populations had rheumatoid factor; it appears likely that many of these individuals did not see a physician.

During the 1980s, it was recognized that most patients with RA observed in rheumatology clinical settings experienced long-term work disability and premature mortality. Results of clinical trials and short-term treatment periods of a year or less were not applicable to long periods of 5 years or more. Some patients seen in usual rheumatology clinics have a self-limited inflammatory polyarthritis. Self-limited polyarthritis is more common in early arthritis clinics, in which only about half of the patients with symptoms of less than 3 months' duration have a progressive disease. By contrast, most patients with symptoms of RA over more than a year who seek medical attention experience a progressive disease.

During the 1990s, new treatment approaches were advocated to control inflammation as aggressively as possible, with “tight control” aiming for remission. Methotrexate was found to have considerably greater efficacy and safety than other DMARDs, and became the “anchor” drug for RA. At present, early aggressive use of methotrexate with other DMARDs and biologic agents in patients who have inadequate responses is regarded as the appropriate approach to patients with RA. Patients with RA at this time have considerably better clinical status than in earlier decades.

The advantages of “tight control” of inflammation in RA have been documented in six clinical trials, all performed in Europe: FIN-RACo (Finnish Rheumatoid Arthritis Combination Therapy), TICORA (Tight Control of Rheumatoid Arthritis), BeSt (Behandel Strategieen), CAMERA (Computer Assisted Management in Early Rheumatoid Arthritis), CIMESTRA (Ciclosporine, Methotrexate, Steroid in RA), and TICORA-2. These trials demonstrate that regular, frequent quantitative measurement, with directives to change therapy based on quantitative data, rather than traditional nonquantitative clinical impressions, leads to better clinical outcomes. Improved patient status in recent years appears to be based primarily on a treatment strategy of tight control aiming at low disease activity and remission guided by quantitative measures, rather than on any specific agent.

B. Why is Quantitative Clinical Measurement a Prerequisite to Recognize Severe RA Outcomes and Guide New Strategies?

RA differs from many chronic diseases in that a single “gold standard” laboratory test, such as those for hemoglobin, glucose, or cholesterol, is not available to establish a diagnosis, assess severity, monitor therapy, and predict outcomes in all individual patients. Therefore, quantitative assessment of RA (and all rheumatic diseases) requires a pooled index of several measures.

RA indices are based on a Core Data Set of seven measures (Table 1): three from a physician–tender joint count, swollen joint count, physician-assessor global estimate of status; one laboratory test of an acute-phase reactant—either erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP); and three measures from a patient self-report questionnaire—physical function, pain, and patient global estimate of status. The most widely used RA index is the disease activity score 28 (DAS28), which includes four measures: swollen joint count, tender joint count, ESR or CRP, and patient global estimate (Table 1).

C. Why Does Usual Clinical Care of Patients with RA Continue to be Conducted without Quantitative Indices and Measures Other than Laboratory Tests?

Recognition of severe long-term outcomes of RA and adoption of new treatment strategies required advances in quantitative assessment of joint counts, radiographic damage scores, and patient self-report questionnaires to assess physical function and pain. The DAS28 was used in all RA clinical trials to date to document the advantages of tight control. Nonetheless, most clinical rheumatology care continues to be conducted primarily in a nonquantitative manner that has not changed over the last 40 years (other than use of an electronic medical record, which is not an electronic database, in some settings), observed by the author.

<table>
<thead>
<tr>
<th>Measures Included in Indices to Assess Patients with Rheumatoid Arthritis</th>
<th>ACR Core Data Set</th>
<th>DAS28*</th>
<th>CDAI</th>
<th>RAPID3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician-Assessor Measures</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. Tender Joints</td>
<td>0.56 x sq rt (TJC28)</td>
<td>0-28</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>No. Swollen Joints</td>
<td>0.28 x sq rt (SJC28)</td>
<td>0-28</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Physician/Assessor Global Estimate</td>
<td>—</td>
<td>0-10</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Laboratory Measures</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ESR or CRP</td>
<td>0.70 x ln (ESR)</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Patient-Reported Measures</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient Function</td>
<td>—</td>
<td>—</td>
<td>0-10</td>
<td></td>
</tr>
<tr>
<td>Patient Pain</td>
<td>—</td>
<td>—</td>
<td>0-10</td>
<td></td>
</tr>
<tr>
<td>Patient Global Estimate</td>
<td>0.014 x PTGL</td>
<td>0-10</td>
<td>0-10</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>0-10</td>
<td>0-76</td>
<td>0-30</td>
<td></td>
</tr>
</tbody>
</table>

*Calculated at web site: http://www.das-score.nl
It is ironic that RA indices that include clinical measures were developed on the basis of the inadequacy of laboratory tests alone to assess patient status, monitor change, and predict outcomes, but laboratory tests remain generally the only available quantitative data at most clinical rheumatology settings. RA indices are used primarily in clinical trials and other clinical research, but not in most usual care. One important contributory factor involves limitations of clinical RA measures, particularly in busy clinical settings, as discussed briefly below.

1. Limitations of Laboratory Tests in Rheumatology

Laboratory test results in RA (and most rheumatic diseases) differ from many widely-used tests in frequent false positive and false negative results. For example, ESR and CRP are normal at presentation in more than 40% of RA patients, and tests for rheumatoid factor and antibodies to cyclic citrullinated peptides (CCP) are negative in ~30% of new RA patients. Furthermore, laboratory tests usually are not available at the time of a patient visit in many clinical settings. Therefore, laboratory tests do not serve as an effective indicator of status in more than one-third of patients with RA, unlike hemoglobin, glucose, or cholesterol, which can be used in anemia, diabetes, or hyperlipidemia for diagnosis, prognosis, monitoring, and analysis of outcomes in all patients.

2. Limitations of a Joint Count

A careful joint examination is required for a diagnosis of RA, and a formal joint count is the most specific measure to monitor control of inflammation. However, swollen and tender joint counts have a number of limitations. Joint counts have lower sensitivity to detect inflammatory activity than ultrasound or magnetic resonance imaging (MRI). Formal joint counts are poorly reproducible, with a requirement to be performed by the same observer at each visit, although reproducibility can be improved with training. Joint counts are more likely to improve with placebo treatment than the other five RA Core Data Set measures. Therefore, relative efficiencies of joint counts are not higher and often are lower than global and patient measures to distinguish between active and control treatments in clinical trials. Joint counts may improve over 5 years, while joint damage and functional disability may progress.

Perhaps the most important limitation of joint counts in usual clinical practice is the time required, about 90 seconds, to perform a formal, quantitative tender and swollen joint count (Fig. 1). This is a substantial fraction of a 20-minute visit which interrupts discussion between the doctor and patient. Of course, a careful joint examination is required at each visit to assess the level of inflammation for clinical decisions, but an exact count, which is not a robust measure, may not be required. The need for a careful examination, but not necessarily a formal count, may be intuited by most rheumatologists, as most visits to a rheumatologist do not include a formal quantitative joint count.

3. Limitations of Quantitative Radiographic Scoring

A radiograph presents several hypothetical advantages in the assessment of RA, in providing a permanent record and the only virtually pathognomonic evidence of RA. Excellent quantitative scoring methods have been described by Larsen, Sharp, van der Heijde, and others. Information using these scores has been quite instructive to rheumatologists concerning: a natural history of radiographic damage within the first 2 years of disease; improved radiographic outcomes at this time; and prevention of damage through DMARDs, in most patients, and biological agents in the 20% to 30% of patients not controlled adequately with methotrexate and other DMARDs.

However, formal scoring of a radiograph is tedious, requiring at least several minutes. Radiographic scores do not change sufficiently in most individual patients to guide therapy. Radiographic damage is a “lagging indicator” for clinical decisions that should have been made at an earlier time, in a “tight control” strategy designed to prevent radiographic damage.

Radiographs do not detect earliest structural changes in patients with RA; ultrasound and magnetic resonance imaging (MRI) are more sensitive indicators. Once certain levels of radiographic damage are reached with subluxation and deformity, progression of structural change may be inevitable, regardless of control of inflammation from that point forward. Thus, radiographs, and even MRI and ultrasound, are limited in guiding therapy in individual patients, although highly instructive concerning the course of RA in groups of patients.

Figure 1 Summary of the different amounts of time estimated to score various measures to assess rheumatoid arthritis, including a 28-joint count, HAQ (health assessment questionnaire), and RAPID3 (routine assessment of patient index data) 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 (Adapted from Yazici Y, et al. J Rheumatol. 2008;35:603-9. © 2008 The Journal of Rheumatology Publishing Company Limited. With permission.)
D. Why Are the DAS28 and Other Traditional Clinical RA Indices Not Included in Most Usual Patient Care at This Time?

The limitations described above concerning individual measures of RA affect application of indices in usual clinical care. For example, three limitations are seen in application of the DAS28 outside of research settings: a. need for a laboratory test (ESR or CRP), the results of which usually are not available at the visit and are uninformative in many patients; b. complex calculations, which can be performed at an excellent website (http://www.das-score.nl) but nonetheless require 18 seconds; and c. a formal joint count, which requires 90 to 95 seconds.

The clinical disease activity index (CDAI) overcomes two limitations of the DAS28, the requirement for a laboratory test and complex calculations, substituting a physician global estimate for ESR or CRP. Nonetheless, the CDAI requires a formal quantitative swollen and tender joint count, which limits its use in usual care. In view of the above considerations, an index has been developed for usual care, RAPID3, which includes only the three patient-reported Core Data Set measures of physical function, pain, and patient global estimate of status. RAPID3 on the MDHAQ is calculated in 5 to 10 seconds, compared to 90 seconds for a tender and swollen joint count, 106 seconds for a CDAI, and 114 seconds for a DAS28 (Fig. 1, Table 2).

An index that requires less than 10% of the time of a CDAI or DAS28 appears attractive for use in usual care. However, it is necessary to document that RAPID3 is appropriate to assess and monitor patient status in order to serve as a guide to tight control of inflammation. Evidence that RAPID3 provides similar information to DAS28 and CDAI, and, therefore, might provide a quantitative guide to tight control of RA in usual clinical care, analogous to DAS28 in clinical trials, is summarized below.

E. Rationale for RAPID3 as a Guide to Help Rheumatologists Achieve Tight Control of RA

1. Similar Relative Efficiencies of Patient-Reported Measures to Joint Counts and Laboratory Tests, to Distinguish Active from Control Treatments in RA Clinical Trials

The seven RA Core Data Set measures have been analyzed for their efficiency to distinguish active from control treatments, by comparing each of the other six measures to a tender joint count as the referent measure. Patient questionnaire measures had relative efficiencies similar to or greater than swollen and tender joint counts or laboratory tests in all studies reported for clinical trials of methotrexate, leflunomide, anakinra, adalimumab, abatacept, and infliximab. For example, in four adalimumab clinical trials, physical function on the HAQ was more efficient than a tender joint count to distinguish between arithmetic changes in patients who received active versus control treatments in three of four trials, pain in three of four trials, and patient global estimate in four of four trials (Fig. 2). Relative efficiencies greater than those observed for swollen joint count were seen according to arithmetic changes for HAQ physical function in three of four trials, pain in three of four trials, and patient global estimate in two of four trials.

In analyses of percentage changes, relative efficiencies were greater than for tender joint count for HAQ physical function in two of four, pain in two of four, and patient global estimate in four of four clinical trials; relative efficiencies greater than for swollen joint count were seen in three of four, two of four, and three of four trials, for HAQ physical function, pain, and patient global estimate, respectively. Relative efficiencies of the three patient measures were also greater than for CRP for arithmetic change in three of four trials, and for percentage change in one of four. Therefore, patient measures have capacities similar to capacities of joint counts and CRP to distinguish active from control treatment in these four clinical trials.

![Figure 2](https://example.com/figure2.png)

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. (Adapted from Pincus T, Amara I, Segurado OG, et al. J Rheumatol. 2008;35:201-5. © 2008 The Journal of Rheumatology Publishing Company Limited. With permission.)
2. RAPID3 Is Correlated Significantly with DAS28 and CDAI

In 285 patients seen in usual care, the Spearman rank order correlation coefficient for DAS28 compared with RAPID3 was 0.66, and for CDAI compared with RAPID3 was 0.74 (p < 0.001) (Fig. 3).88 The high correlation of DAS28 and CDAI with RAPID3 is noteworthy, as RAPID3 shares only one of the four measures with DAS28 and CDAI (patient global estimate of status). The level of these correlation coefficients is higher than seen for the correlation coefficient of 0.51 for ESR with CRP, in the same study database. ESR and CRP are regarded as measures of a similar construct of inflammation. Similarly, RAPID3 measures a similar construct of RA clinical status as DAS28 and CDAI.

3. RAPID3 Distinguishes Active from Control Treatments as Efficiently as DAS28 and CDAI in Clinical Trials

The capacity of RAPID3 to distinguish active from control treatments has been found similar to that of DAS28 and CDAI in clinical trials of methotrexate,86 leflunomide,86 adalimumab,87 abatacept,85 infliximab,49 and certolizumab.70 For example, in the AIM (Abatacept in Inadequate Responders to Methotrexate) trial, the percentage improvement with abatacept was 41.4% according to DAS28 and 47.5% according to RAPID3, versus 21.0% for DAS28 and 23.4% for RAPID3 with control treatment. Differences between treatment arms were 20.3% for DAS28 and 24.0% for RAPID3 (Fig. 4).85 In the ATTAIN (Abatacept Trial in Treatment of Anti-TNF Inadequate Responders) trial, the percentage improvement with abatacept was 28.3% according to DAS28 and 34.7% according to RAPID3, versus 9.4% for DAS28 and 9.9% for RAPID3 with control treatment. Differences between treatment arms were 19.0% for DAS28 and 24.9% for RAPID3 (Fig. 4).85

These data indicate that RAPID3 distinguishes active from control treatments at levels comparable to DAS28 and CDAI. Similar observations have been made in clinical trials of other biological agents,69,70,87 as might be anticipated from comparable relative efficiencies of the individual RA Core Data Set measures described above.

4. RAPID3 Yields Similar Categories for High, Moderate, and Low Activity and Remission, Compared to DAS28 and CDAI in Clinical Care

Categories have been established for high, moderate, and low disease activity and remission for DAS28 and CDAI (Table 3). For DAS28, high is greater than 5.1, moderate 3.21 to 5.1, low 2.61 to 3.2, and remission less than or equal to 2.6; for CDAI, high is greater than 22, moderate 10.1 to 22, low 2.9 to 10, and remission less than or equal to 2.8 (Table 3). Proposed RAPID3 severity categories were reported originally on a 0-10 scale. Since that time, it has been found that RAPID3 scores on a 0-30 scale can be calculated in about half the time as converting to a 0-10 scale (5 versus 10 seconds),84 so the numbers given here are three-fold greater (no longer being divided by three) as in previous publications: high severity is greater than 12, moderate is 6.1 to 12, low

<table>
<thead>
<tr>
<th>Categories of Disease Activity/Severity</th>
<th>DAS28 (0-10)</th>
<th>CDAI (0-76)</th>
<th>RAPID3 (0-30)</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>&gt; 5.1</td>
<td>&gt; 22</td>
<td>&gt; 12</td>
</tr>
<tr>
<td>Moderate</td>
<td>3.21-5.1</td>
<td>10.1-22.0</td>
<td>6.1-12.0</td>
</tr>
<tr>
<td>Low</td>
<td>2.61-3.2</td>
<td>2.9-10.0</td>
<td>3.1-6.0</td>
</tr>
<tr>
<td>Remission</td>
<td>0-2.6</td>
<td>0-2.8</td>
<td>0-3.0</td>
</tr>
</tbody>
</table>
is 3.1 to 6, and near-remission is less than or equal to 3.

Most of 285 patients seen in three clinical settings who met criteria for each of four disease severity categories according to RAPID3 scores were found to meet similar activity categories of DAS28 and CDAI scores (Table 4). Overall, 81% to 84% of patients who met DAS28 or CDAI moderate-high activity criteria met similar RAPID3 severity criteria, and 68% to 70% who met DAS28 or CDAI low activity-remission criteria met similar RAPID3 criteria. Again, RAPID3 was as informative as indices that include a physician-assessor joint count, a laboratory test, or physician-assessor global estimate.

5. Feasibility of RAPID3 and MDHAQ in Usual Clinical Care

The experience of many clinicians with patient questionnaires is generally based on rather tedious and lengthy instruments developed for clinical research, rather than to guide routine patient care (Table 5). In clinical trials and most other clinical research, a patient questionnaire is recognized as a necessary component of the research protocol, which does not contribute to clinical decisions or other aspects of care. Indeed, in a clinical trial situation, the assessor is instructed not to examine patient responses, rather than to review responses with the patient.

By contrast, the MDHAQ has been designed to facilitate a clinical encounter with better information for patient and physician (Table 6). The MDHAQ occupies only two sides of a single sheet of paper. The front side includes scores for physical function, pain, global status, RAPID3, psychological distress, and a self-report RADAI (rheumatoid arthritis disease activity index) joint count. The reverse side includes morning stiffness, review of systems, recent medical and select personal history (including surgeries, hospitalizations, trauma, drug side-effects), and change in medication, physician, insurance, marital status, residence, employment status, and work duties. The most prominent quantitative measures are regarded as “vital signs” for management of chronic diseases and health maintenance that should be available at all visits of all patients with any disease, particularly a rheumatic disease: physical function, pain, smoking status, exercise status, fatigue, and patient global estimate of status.

Scoring of RAPID3 is facilitated by: a. scoring templates

### Table 4 RAPID3 Scores Compared to DAS28 and CDAI in 285 Patients at Three Clinical Rheumatology Sites. All Percentages Are Row Percentages, Except Total in Rightmost Column (Column Percentages)*

| A. DAS28 vs RAPID3 | 
| RAPID3 Scores (0–30) | > 12 | 6.1-12.0 | 3.1-6.0 | 0-3.0 | Total |
|---------------------|----------------------------------|---------|---------|---------|---------|-------|
| DAS28               | > 5.1 = High activity            | 37 (74%)| 11 (22%)| 2 (2%)  | 2 (2%)  | 50 (17%)|
|                     | 3.21-5.1 = Moderate activity     | 39 (43%)| 27 (30%)| 16 (18%)| 8 (9%)  | 90 (32%)|
|                     | 2.61-3.2 = Low activity          | 4 (10%) | 15 (38%)| 10 (25%)| 11 (27%)| 40 (14%)|
|                     | 0-2.6 = Remission                | 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                             |         |         |         |         |        |
| B. CDAI vs RAPID3   | 
| RAPID3 Scores (0–30) | > 12 | 6.1-12.0 | 3.1-6.0 | 0-3.0 | Total |
| CDAI                | > 22 = High activity             | 39 (78%)| 9 (18%) | 2 (2%)  | 1 (2%)  | 50 (17%)|
|                     | 10.1-22.0 = Moderate activity     | 36 (40%)| 33 (36%)| 15 (17%)| 6 (7%)  | 90 (32%)|
|                     | 2.9-10.0 = Low activity           | 15 (16%)| 28 (30%)| 25 (27%)| 25 (27%)| 93 (33%)|
|                     | 0-2.8 = Remission                 | 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                             |         |         |         |         |        |


### Table 5 Patient Questionnaires in Clinical Research Versus Clinical Care

<table>
<thead>
<tr>
<th>Clinical Research</th>
<th>Clinical Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long, 20-60 minutes</td>
<td>Two-page (single sheet of paper), under 10 minutes</td>
</tr>
<tr>
<td>Requires staff time</td>
<td>Saves time for MD</td>
</tr>
<tr>
<td>Complex scoring</td>
<td>Scoring &lt; 5-10 seconds</td>
</tr>
<tr>
<td>Clinician sends to data center, does not review data</td>
<td>Clinician reviews data with patient, enters onto flow-sheet</td>
</tr>
<tr>
<td>Data unknown at visit</td>
<td>Adds to clinical decisions</td>
</tr>
<tr>
<td>Selected patients</td>
<td>All patients</td>
</tr>
<tr>
<td>Research agenda</td>
<td>Quality improvement agenda</td>
</tr>
</tbody>
</table>
for physical function to convert a 0-3 score to 0-10; b. pain, global estimate and fatigue visual analog scales as 21 circles rather than a 10-centimeter line, so a ruler is not needed; c. boxes to enter scores for the three components of RAPID3; and d. a box for the index total score. A two-sheet (four-page) version is available for new patients, which includes features of a standard new patient history, including a complete past medical history, family history, and medication history. The single-sheet version is available for follow-up visits, and many clinical settings choose to use the single-page version for new patients as well.

Management of RAPID3 is easily implemented in standard clinical care settings. Each patient is given an MDHAQ by the receptionist when registering for each visit. The patient spends 5 to 10 minutes completing the questionnaire, which helps the patient to focus on the clinical encounter, rather than being distracted by irrelevant reading material. The process itself may enrich the medical encounter. MD-HAQ data contributed importantly to the capacity to document quantitatively, rather than by “gestalt” impressions, that clinical status in RA patients was substantially better in 2000 compared to 1985.25

F. Potential Limitations of Patient Questionnaires

As with other measures of RA status, patient questionnaires have limitations. The primary concerns are cultural. For example, in a report from a clinical setting with a diverse

<table>
<thead>
<tr>
<th>Table 6</th>
<th>Features of MDHAQ to Enhance Feasibility for Routine Use in Clinic and Scoring RAPID3</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. General Features</td>
<td></td>
</tr>
<tr>
<td>1. Only a single sheet of paper – 2 sides</td>
<td></td>
</tr>
<tr>
<td>2. Vital signs</td>
<td></td>
</tr>
<tr>
<td>a) Physical function</td>
<td></td>
</tr>
<tr>
<td>b) Pain</td>
<td></td>
</tr>
<tr>
<td>c) Smoking status</td>
<td></td>
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<tr>
<td>d) Exercise status</td>
<td></td>
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<tr>
<td>e) Fatigue</td>
<td></td>
</tr>
<tr>
<td>f) Patient global estimate of status</td>
<td></td>
</tr>
<tr>
<td>3. Rheumatology data</td>
<td></td>
</tr>
<tr>
<td>a) Self-report RADAI joint count</td>
<td></td>
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<tr>
<td>b) Morning stiffness</td>
<td></td>
</tr>
<tr>
<td>4. Medical data</td>
<td></td>
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<tr>
<td>a) Change in patient clinical status</td>
<td></td>
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<tr>
<td>b) Review of systems</td>
<td></td>
</tr>
<tr>
<td>c) Recent medical history: surgeries, hospitalizations, trauma, drug side effects, change in medications, physicians, insurance, marital status, residence, employment status, work duties</td>
<td></td>
</tr>
<tr>
<td>B. Scoring RAPID3</td>
<td></td>
</tr>
<tr>
<td>1. Scoring templates for physical function, to convert 0-3 to 0-10 score for 10 activities (8 from the HAQ)</td>
<td></td>
</tr>
<tr>
<td>2. Pain, global estimate of status, and fatigue visual analog scales (VAS) as 21 circles rather than a 10-centimeter line – no ruler is needed</td>
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<td>3. Boxes to enter scores for RAPID3 components, and RAPID3 composite index</td>
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<th>Misperceptions Frequently Expressed as Reasons for Not Using Patient Self-Report Questionnaires in Usual Clinical Care</th>
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<td>1. “Patient questionnaires add extra time and interfere with patient flow.”</td>
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<td>5. “Patient questionnaire data don’t give me as good information to guide clinical decisions and prognosis as traditional radiographic or laboratory measures.”</td>
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<td>8. “Doesn’t a patient questionnaire eliminate the need to examine patients?”</td>
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clinical population, highest scores for pain were seen among Latino patients, followed by Caucasian and African-American patients, with lowest scores among Asian patients. Females report higher scores for all self-report measures, and also have higher joint counts and ESR, than males. However, males have shorter survival, so these phenomena in questionnaire scores may represent, in large part, an ascertainment bias.

Limitations of a questionnaire can be offset, in part, by assessment of functional status using physical measures, such as grip strength and walking time. However, physical measures are less significant than patient questionnaire scores in the prognosis of work disability and mortality. Some of the reasons given (Table 7), and explanations of why they are largely misconceptions, are presented below.

### G. Some Misconceptions Concerning Patient Questionnaires in Usual Clinical Care

Several reports have reviewed reasons expressed by physicians for not using patient questionnaires. Some of the reasons given (Table 7), and explanations of why they are largely misconceptions, are presented below.

1. “Patient Questionnaires Add Extra Time and Interfere with Patient Flow”

Completion of an MDHAQ by each patient in usual clinical care adds almost no burden to patient flow, if the questionnaire is distributed when the patient registers for the visit, and is completed by the patient in the waiting room. The patient generally completes the questionnaire in 5 to 10 minutes prior to being seen in the examination room. A health professional or receptionist can score the MDHAQ in 5 to 10 seconds.

2. “Many Patients Will Object to Completing Questionnaires”

Of course, most people initially do not like to be asked to do anything that they have not done previously, such as completing a questionnaire in the waiting room. Furthermore, if the staff projects an attitude that this is a “necessary evil,” “for research,” or “to document for insurance,” and the doctor does not review the questionnaire with the patient, interest is quickly lost. However, staff is responsive to the clinician, and if the clinician indicates the value of the questionnaire by reviewing the contents with the patient, patients and staff quickly understand that this is an important component of their medical care.

Many patients say that they find completing a questionnaire useful for the clinical encounter with the physician. It is unusual, in settings where questionnaires are used routinely, for the patient to say at the end of the visit, “Oh, Doctor, I forgot to tell you...,” which is not uncommon in usual care settings.

Of course, occasionally a patient will object to completing a questionnaire, just as on rare occasion some patients are unwilling to have blood tests or radiographs. The patient is always to be accommodated. However, almost all patients do not object and, after several visits, recognize the questionnaire as helpful for their medical care.

3. “How Can I Monitor a Patient Quantitatively Without a Joint Count?”

A formal joint count is the most specific measure to assess inflammation in patients with RA. However, many limitations of a formal joint count have been noted above. The greater specificity of a measure does not necessarily indicate greater sensitivity to change, compared to a less-specific measure. Furthermore, a less-specific measure appears preferable to no quantitative measure at all, other than a laboratory test, in documentation of patient status and change in status to guide clinical decisions.

4. “Patient Questionnaire Scores Are Influenced by Irreversible Damage, Unlike Joint Counts, So They Are Not as Sensitive to Control of Inflammation”

An important concern is that patient questionnaires reflect “irreversible” changes, analogous to radiographs, which might compromise their sensitivity to change with treatment. The evidence of similar relative efficiencies of all Core Data Set measures to distinguish active from control treatments in clinical trials (Fig. 2) indicates that patient measures are no more likely to be influenced by irreversible changes than joint counts or CRP; as questionnaire scores change as much as joint counts or CRP over short periods, to document control of inflammation.

5. “Patient Questionnaire Data Do Not Give Me as Good Information to Guide Clinical Decisions and Prognosis as Traditional Radiographic or Laboratory Measures”

The traditional biomedical model, the dominant paradigm of 20th-century medicine, values radiographs and laboratory tests as considerably more informative than patient questionnaires. However, patient questionnaires are more significant in predicting long-term work disability, costs, and premature mortality than radiographs or laboratory tests. Therefore, the patient questionnaire can be as useful as any measure in clinical care. Furthermore, patient questionnaires are far less expensive than other measures.

6. “The MDHAQ Is Useful Only in RA and Not in Other Rheumatic Diseases”

Almost all patients who see a rheumatologist are likely to have problems concerning physical function, pain, global estimate of status, and fatigue. Furthermore, as noted above, smoking and patient exercise status are regarded as “vital
signs,” of which all physicians should be aware, and all patients require a review of systems and recent medical history, as noted above. The MDHAQ is useful in patients with all rheumatic diseases.101

7. “Patient Questionnaires Should Be Used Only at Certain Intervals Rather Than at Each Visit”
Some rheumatologists suggest that they would like to administer the questionnaire selectively, e.g., only to people with RA or only every 3 months. Such approaches generally fail, for several reasons. First, the diagnosis is unknown in new patients (and sometimes in returning patients). Long-term studies indicate that if patients with any rheumatic disease are monitored over a decade or longer, at least a few have a change in diagnosis. More important, asking the receptionist to recognize whether or not a patient should be given a questionnaire adds complexity that often generates complaints from the staff, as a questionnaire is regarded as a burden rather than a routine matter.

The most efficient method to use the MDHAQ in usual care is for the receptionist to distribute the questionnaire to every patient at every visit. Any other strategy appears to add too much complexity for implementation in busy clinical settings. Most patients are seen in rheumatology clinical settings every 2 to 6 months. An unusual patient may be seen as often as over a 1- or 2-week interval. If there is a reason for a patient to be seen frequently, there is even more of a reason to assess clinical status quantitatively, to recognize improvement or worsening.

8. “A Patient Questionnaire Eliminates the Need to Examine the Patient’s Joints”
The patient questionnaire is an adjunct to care, just as a radiograph or laboratory test. All visits of patients to a rheumatologist must include a careful physical examination, including a joint examination. It is suggested that a formal quantitative joint count may not be necessary, as a patient questionnaire provides quantitative data of comparable value to monitor patients with far less physician time.

9. “A Patient Questionnaire Replaces Conversation and Interferes with Doctor-Patient Communication”
The patient questionnaire not only does not interfere with doctor-patient communication, it adds to it by eliminating a need to collect factual information and allowing a focus on the patient’s medical concerns. A careful history is needed at every patient visit, but factual information can be provided by a patient questionnaire and save considerable time for the doctor (and patient).

It is recognized that, at this time, many patients with RA have such good clinical status that they do not require lengthy visits, but nonetheless require careful monitoring of therapy with methotrexate or biological agents. Some of these patients are anxious to get back to work quickly, and do not necessarily require a lengthy visit with extensive conversation. These patients can be accommodated, using the patient questionnaire to add to the efficiency of their care.

10. “Electronic Data Capture Is Invariably More Effective Than Pencil and Paper”
Many suggest that it is desirable to enter the data directly into an electronic database, rather than to use pencil and paper. However, if the clinician is involved, there is no way that a computer can be used to calculate a score more quickly than 5 to 10 seconds. Of course, direct entry into a computer can provide a database. However, such procedures appear too complex in most clinical settings at this time, other than in specialized clinics with sophisticated computer systems. In general, pencil and paper are much more efficient than a computer, despite appearances and even demonstrations to the contrary.

As noted above, an electronic medical record is not an electronic database. The author maintained a database of every clinical visit over 25 years. A physician or other health professional should be careful about the overuse of technology—many attractive options are quite expensive and based on “hotel-based medicine”102 rather than actual clinical care.

11. “An MDHAQ Cannot Be Completed by Patients of Low Education Level”
The MDHAQ is quite patient-friendly, and has been completed by patients of all levels of education.103 Patients of low education generally have poorer status on the questionnaire. However, the gradient of poor to better status from lower to higher education is similar for responses on a questionnaire, joint counts, and ESR, reflecting poorer overall clinical status of patients with lower socioeconomic status.104 Illiterate patients require some help from a family member, but generally have a “literacy partner” in order to be able to get to the clinic and function in society in general.105 Although many are skeptical, easy completion of an MDHAQ is usual by most patients in all types of clinical settings.

12. “RAPID3 Responses Are Used to Trigger Automatic Therapeutic Decisions”
The introduction of quantitative measures into clinical rheumatology may suggest essentially “automatic” responses, such as “anyone with a high RAPID3 score greater than 12 (or a DAS28 greater than 5.1, or a CDAI greater than 22) must have a change in DMARD or biologic therapy.” However, any measure or index should serve only as a guide to clinical judgment, as the situations of individual patients may differ widely. Nonetheless, clinical judgment is greatly enhanced by availability of quantitative measures.

For example, a patient may have an elevated ESR or DAS28 compared to a previous visit, which may reflect infection or development of a lymphoma, rather than a flare of RA. Similarly, a patient may sustain a compression fracture, raising global scores, and thereby raising RAPID3,
DAS28, or CDAI scores, but not require a change in therapy. A history and physical examination, and laboratory tests, are needed to understand the basis for a change in any quantitative questionnaire measure.

All quantitative measures, ranging from temperature to pulse to hemoglobin, must be viewed in the context of the individual patient, in formulating clinical decisions. This point cannot be emphasized too strongly, particularly as non-physicians with no experience in patient care are increasingly given authority to determine clinical activities, therapies, and even “quality” of medical care. All medical care must be tailored to each individual patient; global recommendations, including levels of RA indices that may suggest changes in therapy, must be viewed as guidelines and not as absolute directives.

Conclusion
This essay has attempted to provide a brief summary of the rationale for using MDHAQ-RAPID3 to help guide clinical care in usual rheumatology clinical practice. Further details concerning strategies for distribution and management of the MDHAQ and RAPID3 are presented in a previous essay. The MDHAQ is easily completed by patients, and a RAPID3 score gives results that are similar to widely-recognized indices, DAS28 and CDAI, that require a formal joint count.

Use of MDHAQ-RAPID3 by all rheumatologists could advance clinical rheumatology from a largely descriptive field (outside of clinical trials and other clinical research studies), so that all care can be conducted in quantitative rather than descriptive terms. Clinical rheumatology could then have a firmer scientific basis, with accurate assessment of patient status at each visit, better guidance for clinical monitoring, improved patient outcomes, and increased respect as a quantitative science. Nonetheless, it must be emphasized that all quantitative measures, ranging from hemoglobin to ESR to RAPID3, cannot be applied according to a simple formula, as clinical judgment is required to interpret quantitative data in decisions in individual patients.

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