# Assessment of quality of rheumatoid arthritis care requires joint count and/or patient questionnaire data not found in a usual medical record: examples from studies of premature mortality, changes in clinical status between 1985 and 2000, and a QUEST-RA global perspective

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**ABSTRACT**

*Quality of care of many diseases, such as diabetes, hypertension, hyperlipidemia, and osteoporosis, can be assessed effectively from information in usual medical records concerning blood tests, blood pressure, bone density, etc. However, quality of care of rheumatoid arthritis (RA), as well as most rheumatic diseases, cannot be assessed from usual medical records. The primary basis for this problem involves limitations of laboratory tests and the absence of a single "gold standard" measure in RA Therefore, indices which include laboratory tests, joint counts, and patient questionnaires have been developed. These indices are collected in all RA clinical trials and other clinical research, but not in usual clinical care, a phenomenon which may limit severely possible assessment and improvement of quality and patient outcomes. Patient questionnaires and joint counts, rather than laboratory tests or radiographs in a medical record, are the best measures to assess and monitor RA patient status. Patient questionnaires are the most significant clinical prognostic markers for severe long-term RA outcomes, such as work disability, costs and premature mortality, and are more cost-effective and easily-collected than formal quantitative joint counts in busy clinical settings. The value of patient questionnaires and joint counts in RA is reviewed in three examples from the authors' research concerning premature mortality in RA, changes in patient clinical status between 1985 and 2000, and a QUEST-RA global perspective, to better evaluate the structure, processes, and outcomes of RA care.*

## Introduction

Quality of care of many chronic diseases, such as diabetes, hyperlipidemia, hypertension, and osteoporosis, can be assessed effectively from a usual medical record. Blood tests for glucose, hemoglobin A1C, cholesterol, blood pressure, bone density, major complications, and other data in a medical record are available to assess indicators of quality. The data can be used to develop possible goals to improve quality and document the extent to which these goals might or might not be met.

By contrast, quantitative data from the usual medical record generally are quite limited to assess quality of care for patients with rheumatoid arthritis (RA), as well as most rheumatic diseases. The absence of these data may limit possible improvement of quality and outcomes, and possible assessment and documentation of such improvement. Several bases may be cited for limitations of the usual medical record to assess quality in RA:

Laboratory tests, the traditional source of the most informative data regarding patient status in many diseases, often are not informative about patient status in RA, and give frequent "false-positive" and "false-negative' diagnostic results. For example, while more than 50% of patients who present with RA have a positive test for rheumatoid factor (RF), antibodies to cyclic citrullinated proteins (anti-CCP), elevated erythrocyte sedimentation rate (ESR), or C-reactive protein (CRP), 30-40% of patients have normal RF, anti-CCP, ESR or CRP levels (1, 2). Although textbooks suggest that positive laboratory tests are associated with more severe clinical status, this appears true

only for radiographs (3), but not for functional status outcomes, work disability, mortality, or use of methotrexate or biological agents (4). Laboratory data certainly are essential for studies of pathogenesis and for development of new therapies, and of possible value to assess quality in *groups* of patients, but severely limited in clinical management and assessment of quality in *individual* patients. Furthermore, many people with positive RF and most people with positive anti-nuclear antibody (ANA) tests do not have a disease, but merely an abnormal laboratory test (5, 6).

In addition to the absence of a definitive laboratory test, no single "gold standard" measure (such as blood pressure or serum cholesterol) is available in RA for diagnosis, assessment and monitoring in all patients in clinical trials, clinical research and clinical care. Therefore, pooled indices of multiple measures (7) such as the American College of Rheumatology (ACR) Core Data Set (8), disease activity score (DAS) (9), and clinical disease activity index (CDAI) (10) have been developed.

Although one or more of these indices is incorporated into all clinical trials and most other clinical research, none is widely used by most rheumatologists in regular clinical care. All of these indices require a formal *quantitative* joint count, which is not performed in most regular care of RA patients (11), although rheumatologists generally perform a careful *qualitative* joint evaluation. Tender and swollen joint counts are tedious to perform, have poor reliability, and may indicate improvement in patient status while progressive damage is seen (12). Although quantitative joint counts comprise 2 of 7 Core Data Set measures and 2 of 4 DAS and CDAI measures, generally they are not available in most medical records.

Patient questionnaire scores for physical function, pain, global status and fatigue are increasingly recognized to be of considerable value for assessment and monitoring of patients with RA (4, 12, 13). Patient questionnaire measures comprise 3 of 7 core data set measures and 1 of 4 DAS and CDAI measures. Questionnaire scores for physical function provide the most significant prognostic clinical measures for severe outcomes of RA, such as work disability, costs, and premature mortality. Indices of only patient data distinguish active from control treatments in clinical trials as effectively as indices that include joint counts, such as the DAS (14-16). However, despite their documented value to assess, monitor, and predict patient status in RA, most regular care does not include patient questionnaires (17). Therefore, while questionnaires may be the most informative measures to assess quality of care (13), such data are available in only a handful of usual medical records.

Regular care of patients with RA remains conducted primarily according to "Gestalt" qualitative impressions rather than quantitative data [other than laboratory tests (11, 18)], except in relatively few clinical settings (19-26). Therefore, the medical record, in which the only quantitative data generally available are laboratory tests, is severely limited to study quality of care. Rheumatologists and quality researchers generally have approached this problem by making best use of available information in the medical record, such as whether a patient diagnosed with RA is treated with disease-modifying anti-rheumatic drugs (DMARDs) or has appropriate monitoring of the therapy (27, 28). These indicators generally are surrogate process measures, which are quite limited to assess quality. Optimal assessment of quality in RA care would be enhanced by efforts to encourage rheumatologists to collect quantitative data from patients concerning functional status, pain, fatigue and global status, to assess patient status as well as outcomes.

This chapter addresses the case for inclusion of measures not found in the usual medical record, patient questionnaire scores and joint counts, to improve assessment of the quality of care in RA and the level of quality itself. We focus on examples from our own clinical research which illustrate the value of patient data from questionnaires and joint counts, recognizing many contributions of others discussed in previous reviews (4, 12, 29-33) that cannot be described here because of space limitations. We summarize some lessons from quantitative assessment of patients with RA in regular clinical care which support the importance of patient questionnaire and joint count measures in the three domains of quality – structure, process and outcomes (34) – concerning three topics (Table I): 1) prognosis for premature mortality; 2) improved status of patients at this time compared

**Table I.** Possible relevance of three types of studies presented to analyses of and advances in the quality of the structure, process and outcomes of care for patients with RA.

| Study | Structure | Process | Outcomes |
|---|---|---|---|
| Premature mortality in RA (40, 49, 50, 54) | Impetus to develop more effective DMARDs such as methotrexate and biological agents. | Use of DMARDs early in disease rather than after radiographic damage was seen. | Focus on poor long-term outcomes in regular care rather than on short-term improvements in clinical trials. |
| Better patient status in the 2000s compared to the 1980s (25) | Emergence of methotrexate as the anchor drug for care, and biological agents in the minority of patients who do not respond to methotrexate. | Early intervention with a goal of remission rather than a partial improvement in clinical status. | Evidence of improved outcome from a limited number of RA treatment settings. |
| QUEST-RA international database (35, 120). | The importance of documentation that RA inflammatory activity is associated with macro-economic variables in 20 countries. | Patients in countries in which biologic agents are less available have poorer clinical status. | Correlations of clinical status with GDP in various countries, which has important implications for the efforts of rheumatologists to improve quality of care. |

to previous decades; 3) an international perspective based on recent data from a Quantitative Patient Questionnaires in Standard Clinical Care of Patients with Rheumatoid Arthritis (QUEST-RA) program concerning patients from regular care at 62 sites in 22 countries (35).

### Prognosis of premature mortality in RA

The natural history of untreated or partially treated RA in the 1980s was characterized by radiographic progression (36), severe functional declines (37, 38), work disability (37, 39), and premature mortality (37, 40, 41) in most patients. Premature mortality in RA was not widely appreciated until about 20 years ago for several reasons:

1) A focus on clinical trials indicated efficacy of DMARDs, which were often termed "remission-inducing therapy." However, more than 80% of courses of traditional DMARDs such as gold injections and penicillamine were discontinued within one year, and sustained remission was seen in fewer than 5% of patients over 3 years (19).
2) The acute attributed causes of death in RA generally are similar to those in the general population (40), *e.g.*, of 2,213 deaths at 13 sites reported prior to 1986, 42% were attributed to cardiovascular disease compared to 41% in the general U.S. population (40). Although acute, attributable causes of death in patients with RA were higher for infection, renal disease, pulmonary disease, gastrointestinal disease and RA itself, the overall pattern is similar to the general population.
3) Only a few sites have maintained long-term databases, which are required for longitudinal analysis of the natural history over 5-20 years in patients from regular care. Analyses of such databases indicated that patients with RA had shortened life span by 5-15 years compared to individuals matched for age and sex in the general population (20, 37, 40-44).

In patients with RA monitored after an extensive baseline assessment in 1973, premature mortality over 5 years was predicted significantly by poor clinical status, recognized as the number of affected joints and poor questionnaire scores for physical function in activities of daily living (20, 37, 44-48). Patients who could perform fewer than 80% of activities of daily living without difficulty or had more than 18 affected joints according to a questionnaire (Figure 1) experienced 5-year survivals of about 50% (40, 49, 50), in the range of patients with Stage IV Hodgkin's disease (51) or 3-vessel coronary artery disease (52). Patients with poor clinical status according to a patient questionnaire or with high numbers of affected joints were 3-7.5 times more likely to die over the next 5-15 years than patients with favorable clinical status (44) (Table II), risks at least as great as those seen over 12 years in cardiovascular disease, according to blood pressure and cholesterol (44).

The observation that physical function on a patient questionnaire provides an optimal prognostic marker for mortality in RA has been replicated in many studies (20, 45, 47, 48, 53-55). One example is seen in a cohort of patients established in 1985, designed to include such state-of the-art measurements of clinical status as a 68-joint count, Sharp radiographic score, laboratory studies such as the HLA haplotype and *in vitro* rheumatoid factor production, as well

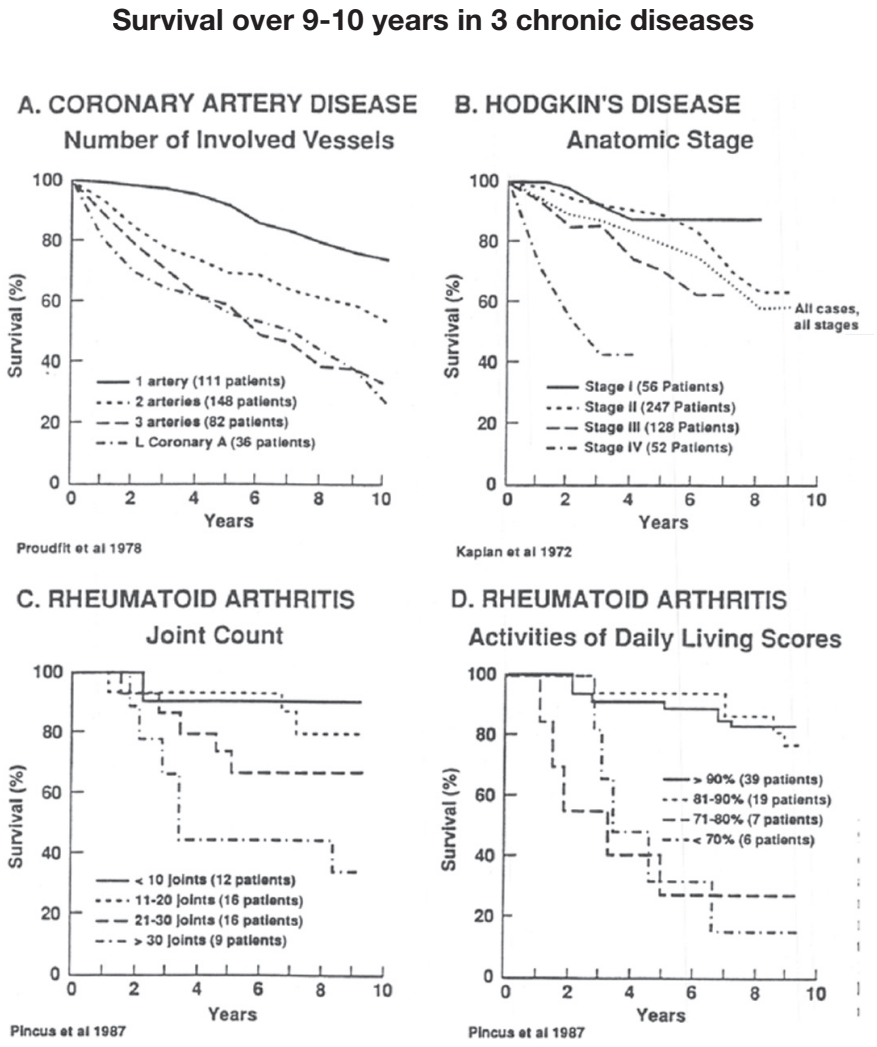


**Fig. 1.** Survival in 3 chronic diseases – coronary artery disease, Hodgkin's disease, and rheumatoid arthritis – according to baseline measures of clinical status: number of involved vessels, anatomic stage, joint count, activities of daily living on a patient questionnaire. [This figure was originally published in the *Journal of Rheumatology,* 1990; 17: 1582-1585 (82), and is reproduced here with the publisher's permission.]

**Table II.** Relative risk (RR) of death over 12-15 years in rheumatoid arthritis (RA) and cardiovascular (CV) disease according to baseline severity indicators.

| Indicator | Baseline severity | RR |
|---|---|---|
| RA: 75 patients, 15 years – Pincus *et al*., *Ann Int Med* 1994; 120: 26 (44). | | |
| Functional status on patient questionnaire | < *vs*.. > 91.5% "with ease" | 2.9:1 |
| Number of involved joints | > *vs*. < 18 joints | 3.0:1 |
| CV disease: 312,000 patients, 12 years – Neaton *et al*., *Arch Int Med* 1992; 52: 56 (128). | | |
| Serum cholesterol | ≥ 245 *vs*. < 182 mg/dL | 2.9:1 |
| Systolic blood pressure | ≥ 142 *vs*. < 118 mmHg | 3.0:1 |
| Diastolic blood pressure | ≥ 92 *vs*. < 76 mmHg | 2.9:1 |
| Smoking | ≥ 26 *vs*. 0 cigarettes/day | 2.9:1 |

Data adjusted for age, sex, education, disease duration.
Source: Pincus *et al*., *Ann Int Med* 1994; 120: 26 (44).

as patient questionnaires. All clinical measures indicated poorer status at baseline in patients who would not survive the five-year period compared to survivors (Table III) (54). These results might have been expected, although it may be regarded as an advance to express poor versus good clinical status in *quantitative* rather than *qualitative*, "Gestalt" terms (54).

In Cox regressions, the three independent predictors of 5-year mortality were age, comorbidities, and functional status on a modified health assessment questionnaire (MHAQ) (54) (Table IV). Traditional radiographic and laboratory measures tests were of low or no significance in univariate analyses and were not entered into multivariate models (Table IV). All studies which include a patient self-report questionnaire indicate that this measure, rather than a radiographic score or laboratory test, provides the most significant predictor of all severe long-term outcomes, including functional status (37, 38), work disability (56-58), costs (59), joint replacement surgery (60) and premature death (37, 44, 46, 48, 53, 54, 61, 62).

Observations concerning premature mortality in RA may have stimulated improvements in the quality of care over the last two decades through improvements in structure – an impetus to develop more effective DMARDs such as methotrexate and biological agents; process – use of DMARDs early in disease rather than after radiographic damage was seen, as was the practice in the 1980s; and outcomes – a focus on poor long-term outcomes in regular care rather than on short-term improvements in clinical trials (Table I). However, at this time, assessments of quality of RA care continue to focus on information available from medical records, such as laboratory tests and imaging measures, rather than patient questionnaires, which are far more significant in the prognosis of mortality and other severe outcomes. More efforts to encourage collection of the most important outcomes data, rather than efforts to "make the best" of available process data, might provide greater advancements in evaluation of quality of care and improvements in quality itself.

**Table III.** Mean baseline values of measures of activity and damage as possible predictors of mortality 5 years later in 206 patients (54).

| Measure* | Total N =3 206 | Alive N = 169 | Dead N = 37 | *P* value |
|---|---|---|---|---|
| Joint count – Total (42 joints) | 13.4 | 12.8 | 15.9 | 0.04 |
| Swelling (42 joints) | 15.0 | 14.5 | 17.0 | 0.16 |
| Tenderness (42 joints) | 15.9 | 15.6 | 17.4 | 0.38 |
| Limited motion (42 joints) | 9.2 | 8.2 | 13.3 | 0.005 |
| Deformity (42 joints) | 8.1 | 7.6 | 10.5 | 0.11 |
| Pain on motion (42 joints) | 8.9 | 8.4 | 11.1 | 0.09 |
| Radiograph - Total (1-4.33) | 1.23 | 1.20 | 1.36 | 0.20 |
| Erosion (1-4) | 1.46 | 1.40 | 1.75 | 0.06 |
| Joint space narrowing (1-5) | 2.19 | 2.16 | 2.31 | 0.47 |
| Malalignment | 0.21 | 0.20 | 0.28 | 0.34 |
| Laboratory testing | | | | |
| Rheumatoid factor titer | 416 | 385 | 764 | 0.07 |
| ESR (mm/hour) | 36.4 | 33.8 | 48.3 | 0.004 |
| Physical measures | | | | |
| Grip strength (mmHg) | 104.8 | 108.8 | 86.4 | 0.03 |
| Walk time (seconds) | 11.0 | 10.4 | 14.1 | 0.005 |
| Button test (seconds) | 68.5 | 62.6 | 96.2 | < 0.001 |
| Questionnaire measures | | | | |
| MHAQ ADL (1-4) | 2.04 | 1.98 | 2.32 | 0.005 |
| Patient global status (1-4) | 2.69 | 2.63 | 3.00 | 0.01 |
| Pain-VAS (0-10) | 5.37 | 5.40 | 5.19 | 0.68 |
| Helplessness (1-4) | 2.43 | 2.41 | 2.55 | 0.007 |
| Sociodemographic | | | | |
| Age (years) | 57.0 | 55.1 | 65.5 | < 0.001 |
| Formal education (years) | 10.6 | 10.8 | 9.4 | 0.03 |
| Disease variables | | | | |
| Duration of disease (years) | 9.7 | 9.1 | 12.7 | 0.03 |
| Comorbidities (no.) | 1.27 | 1.10 | 2.11 | < 0.001 |
| ACR Functional Class | 2.23 | 2.16 | 2.56 | < 0.001 |

*ESR: erythrocyte sedimentation rate; MHAQ: modified Health Assessment Questionnaire; ADL: activities of daily living; VAS: visual analog scale; ACR: American College of Rheumatology.
Source: Callahan *et al*., *Arthritis Care Res* 1997; 10: 381 (54).

**Better status of patients in the 2000s compared to 1980s**

Patients with RA have better status in recent years compared to the mid 1980s, according to the Ritchie articular index (63), functional capacity (25, 64), and radiographic scores (65, 66), including lower mortality rates in patients who responded to methotrexate (67, 68). For example, a comprehensive

**Table IV.** Cox Proportional Hazards Model analyses including demographic, functional, self-report, joint count x-ray, laboratory and disease variables (54).

| | Univariate | | Stepwise model | |
|---|---|---|---|---|
| | Relative risk (95% CL)* | *P* value | Relative risk (95% CL) | *P* value |
| Age | 1.07 (1.04, 1.11) | <0.001 | 1.06 (10.3, 1.10) | <0.001 |
| Comorbidity | 1.63 (1.32, 2.00) | <0.001 | 1.40 (1.11, 1.77 | 0.02 |
| MHAQ ADL score** | 2.00 (1.28, 3.12) | 0.002 | 1.76 (1.40, 2.78) | 0.02 |
| Disease duration | 1.04 (1.01, 1.06) | 0.02 | — | — |
| Education | 0.89 (0.82, 0.97) | 0.007 | — | — |
| ESR | 1.01 (1.00, 1.02) | 0.005 | — | — |
| Joint count | 1.02 (0.97, 1.04) | 0.10 | — | — |
| Walk time | 1.03 (1.01, 1.06) | 0.04 | — | — |
| X-ray | 1.40 (0.86, 2.27) | 0.17 | — | — |

*95% CL = 95% confidence limitation
**MHAQ: modified Health Assessment Questionnaire; ADL: activity of daily living; ESR: erythrocyte sedimentation rate.
Source: Callahan *et al*., *Arthritis Care Res* 1997; 10: 381 (54).

cross-sectional quantitative assessment indicated considerably better clinical status in 150 consecutive patients seen by TP in 2000 (1999-2001) compared to 125 consecutive patients seen by the same rheumatologist in 1985 (1984-1986) (Table V, Fig. 2) (25). The median unadjusted number of swollen joints (range 0-28) was 12 in 1985 and 5 in 2000 ($p< 0.001$), median ESR (range 0-150) was 33 in 1985 versus 20 in 2000 ($p= 0.016$), and median modified health assessment questionnaire (MHAQ) scores for functional status (range 0-3) were 1.0 in 1985 compared to 0.4 in year 2000. Median Larsen radiographic scores (range 0-100) were 20 in 1985 compared to 3 in 2000; rheumatoid factor-negative patients were virtually without significant radiographic damage in 2000, and even rheumatoid factor-positive patients with 15 years of disease scored less than 10% of maximum, compared to 30% of maximum in 1985 (Fig. 2).

These differences between 1985 and 2000 data are independent of and not explained by possible differences in age, duration of disease, formal education level, or any other known variable, other than differences in therapies. Thirty-seven percent of patients in the 1985 cohort were taking no DMARDs, compared to 3.3% in the 2000 cohort (Table VI). Only 10.4% of the 1985 cohort was taking methotrexate, compared to 76.7% of the 2000 cohort (25). These data indicate beneficial long-term effects of aggressive treatment strategies, as seen in the Finland Rheumatoid Arthritis Combination Trial (FIN-RACo) (69; 70), BeST trial in early RA (71), and tight control for rheumatoid arthritis (TICORA) study (72).

Management of patients with RA in the 1980s according to a traditional "pyramid" approach (73, 74), in which monotherapy with DMARDs was administered only after evidence was seen of radiographic erosions or permanent damage, was replaced by combination DMARDs (75) and use of methotrexate (76) as the "anchor DMARD" for early intervention (77) (Table VI). There may have been good reasons for avoiding DMARDs in earlier periods, as the available DMARDs such as intramuscular gold and penicillamine were effective over long periods in fewer than 20% of patients, and had severe adverse events, including death from nephritis and aplastic anemia (19). Methotrexate has considerably greater effectiveness and lower toxicities than previously- and currently-available DMARDs, and can be introduced early with a goal of long-term remission (78-82).

More favorable results were seen for both measures of inflammatory activity, which may be improved over time, and measures of damage, which may show simultaneous progression in the same patients (36, 37, 54, 83-91). As with studies of mortality in RA, documentation of improved clinical status

**Table V.** Clinical status measures and therapies in two cohorts of patients with rheumatoid arthritis seen at Vanderbilt University by T. Pincus in 1984-86 ("1985") and 1999-2001 ("2000") (25).

| Clinical status measures* | Cohort | | *P*-value** |
|---|---|---|---|
| | 1985 (N = 125) Median (range) | 2000 (N = 150) Median (range) | |
| Swollen joint count (0-28) | 12 (6, 16) | 5 (2, 10) | < 0.001 |
| Larsen radiographic score (0-100) | 20 (2, 36) | 3 (0, 13) | < 0.001 |
| Erythrocyte sedimentation rate (mm/hr) | 33 (16, 50) | 20 (9, 33) | 0.016 |
| Functional disability score on MHAQ (0-3) | 1.0 (0.6, 1.4) | 0.4 (0.1, 1.0) | < 0.001 |
| DAS28 (0-10) | 5.7 (4.9, 6.5) | 4.4 (3.2, 5.3) | < 0.001 |

*Values depict unadjusted median values and interquartile range; p-values derived from a median regression model adjusted for age, education, duration of disease and rheumatoid factor status.
**$p$-value from Student's $t$-test, Mann-Whitney test, or Chi Square test, as appropriate.
Source: Pincus *et al*., *Arthritis Rheum* 2005; 52:1009 (25).

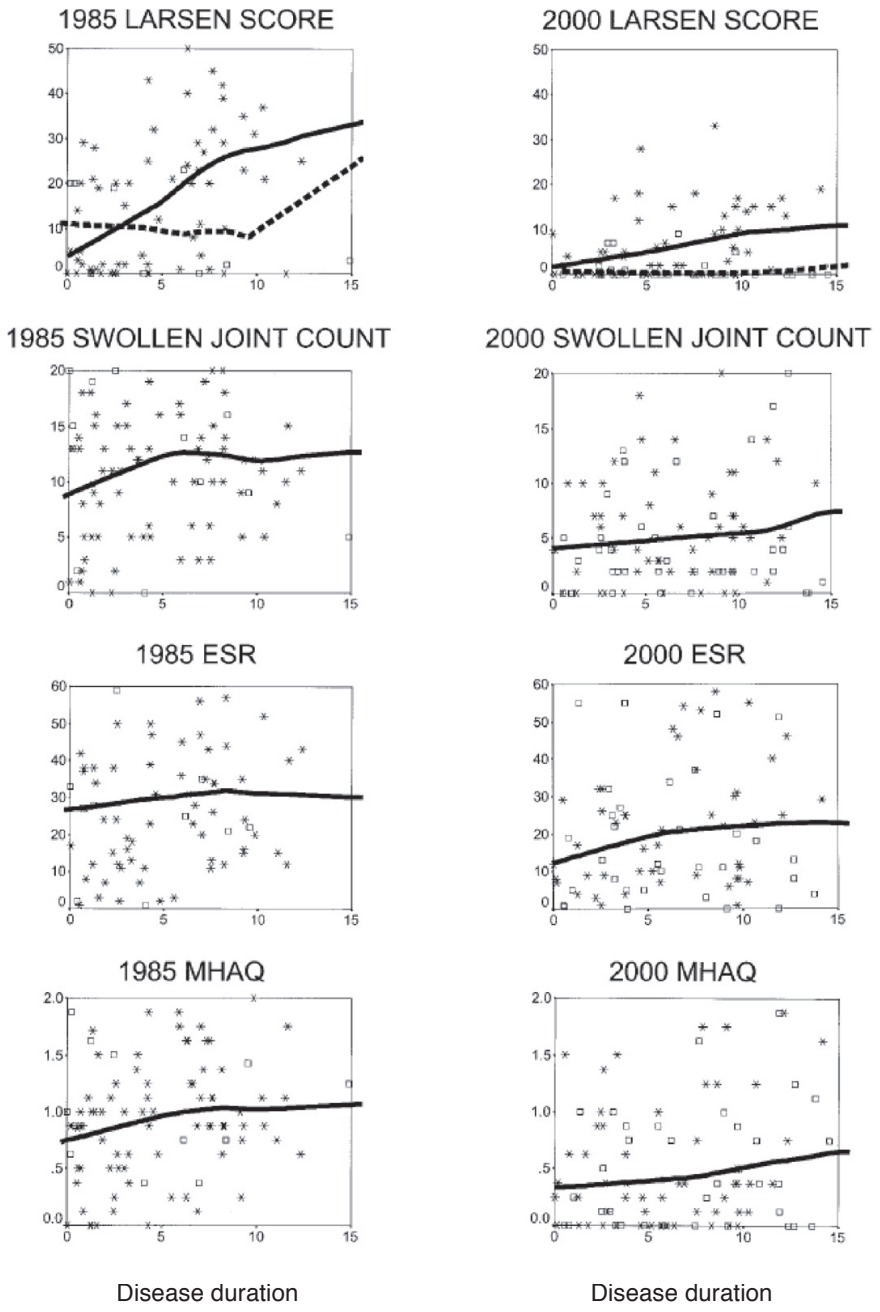


**Fig. 2.** Quantitative measures of clinical status in all patients seen by the same rheumatologist in 1985 and in 2000, including Larsen radiographic score, swollen joint count, erythrocyte sedimentation rate (ESR) and modified health assessment questionnaire (MHAQ). Patients who were positive for rheumatoid factor (RF) are depicted by asterisks, and patients who were negative for RF by squares. Locally weighted scatterplot smoothing regression curves from 0 to 15 years are shown. Two curves for Larsen scores include a solid line for RF-positive patients and a dashed line for RF-negative patients. [This figure was originally published in *Arthritis and Rheumatism,* 2005; 52: 1009 (25), and is reproduced here with the publisher's permission.]

in standard care is not available from randomized controlled clinical trials, which cannot be performed over periods of 10 to 15 years for ethical and logistic reasons (92). Furthermore, although selection bias regarding the therapy given to an individual patient is overcome in clinical trials, inclusion and exclusion criteria and other limitations of the methodology may introduce other types of selection biases which may compromise generalizability and representativeness (2, 93-108).

Comparisons of patients seen in regular care in the 1980s versus the 2000s indicate improvements in the quality of care in the three domains of structure, process and outcomes (34), respectively (Table I): structure – emergence of methotrexate as the anchor drug for care and biological agents in the minority of patients who do not respond to methotrexate; process – early intervention with a goal of remission rather than a partial improvement in clinical status; outcomes – evidence of substantially improved outcomes at least from one treatment setting. A few reports have documented better status of patients with RA in recent years compared to earlier years at other settings (63-68). Nonetheless, quantitative patient questionnaires or joint counts have not been incorporated into regular care at most rheumatology treatment sites, and therefore are not available in most usual medical records. It appears desirable to compare patients in regular care at multiple settings according to quantitative measures (109, 110), and to promote more widespread use of quantitative measures, to improve assessment of quality of care.

### Expanding quantitative assessment of RA in regular care with a global perspective in the QUEST-RA program

A Quantitative Patient Questionnaires in Standard Clinical Care of Patients with Rheumatoid Arthritis (QUEST-RA) program was established in 2005 to promote quantitative assessment in usual clinical care at multiple sites, and to develop a database of RA patients seen in regular care in many countries. The initial design was to assess 100 patients with RA at each of 3 or more sites in different countries. Data collection was begun in January 2005. By July 2007, the program included 5,519 patients from 62 sites in 22 countries (35): Argentina, Canada, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, the Netherlands, Poland, Russia, Serbia, Spain, Sweden, Turkey, the United Kingdom, and the United States. All patients were assessed according to a standard protocol to evaluate RA (SPERA) (111).

**Table VI.** Clinical therapies in two cohorts of patients with rheumatoid arthritis seen at Vanderbilt University by T. Pincus in 1984-86 ("1985") and 1999-2001 ("2000") (25).

| | Cohort | | | |
|---|---|---|---|---|
| | 1985 (N = 125) | | 2000 (N = 150) | |
| Therapy measures* | N | % | N | % |
| No DMARDs, no prednisone | 46 | 36.8% | 5 | 3.3% |
| **Methotrexate + any other drug** | **13** | **10.4%** | **115** | **76.7%** |
| **Prednisone + any other drug** | **64** | **51.2%** | **129** | **86.0%** |
| Prednisone only | 37 | 29.6% | 15 | 10.0% |
| Infliximab + any other drug | 0 | 0 | 3 | 2.0% |

*Values depict number and percentage of patients receiving each therapy in each cohort.
Source: Pincus *et al*., *Arthritis Rheum* 2005; 52: 1009 (25).

Physicians completed 3 one-page forms: a) review of clinical features, including classification criteria, extra-articular features, comorbidities, and relevant surgeries; b) all previous and present DMARDs, their adverse events, and reasons for discontinuation; c) a 42-joint count (112) which includes swollen and tender joints, as well as joints with limited motion or deformity. The review included physician global assessment of disease activity, physician report regarding whether or not the patient had radiographic erosions, and laboratory tests of ESR, CRP and RF values. Disease activity score (DAS28) was calculated for current disease activity (9, 113).

Patients completed a 4-page expanded self-report questionnaire that included items from the Health Assessment Questionnaire (HAQ) (114), the multidimensional HAQ (MDHAQ) (115), HAQ II (116), and Recent-Onset Arthritis Disability (ROAD) questionnaire (117) to assess: functional capacity in activities of daily living; visual analog scales (VAS) for pain, global status and fatigue; Rheumatoid Arthritis Disease Activity Index (RADAI) self-report joint count (118); duration of morning stiffness; life-style choices such as smoking and physical exercise; height and weight for body mass index; and demographic data including years of education and work status (35).

Among the 5,519 patients enrolled as of July 2007, median HAQ score was 1.0 (range 0-3), and median DAS28 score was 4.1 (range 0-10). Considerable variation between countries was seen in median HAQ scores, ranging from 0.3 to 1.6, as well as median pain scores from 2.3 to 5.2, and median patient estimate of global status from 2.0 to 5.3. Significant variation in median DAS28 was seen between countries ($p< 0.001$), ranging from about 3.0 in the Netherlands, Greece, and Finland to 5.6 in Lithuania and Argentina and 6.1 in Serbia (Table VII) (35).

Among 48 sites at which more than 50 patients were enrolled by April 2007, low disease activity of DAS28 <3.2 was seen in more than 50% of patients at 8 sites in 6 countries: the Netherlands, Finland, USA, Greece, Denmark, and Spain (Fig. 3). The data extend observations that most patients at some clinical sites would *not* be eligible for most RA clinical trials due to low disease activity (107, 119). By contrast, more than 50% of patients had DAS28>5.1, indicating high disease activity, in 5 countries, including Latvia, Poland, Argentina, Lithuania and Serbia.

Pronounced inequalities are found among different European Union and other countries in clinical status and therapies (Table VII). Fewer than 20% of patients were currently taking oral glucocorticoids in Denmark and the Netherlands, in contrast to 83% of patients in Lithuania. More than 25% of patients were taking biologic agents in the USA, France, Sweden, Ireland, and Latvia, although the high percentage in some countries may be explained by prior inclusion of some patients in randomized clinical trials of biologic agents. Fewer than 10% of patients were taking biologic agents in Serbia, Estonia, Argentina, Turkey, Poland, and Lithuania (Table VII).

Quantitative measures and therapies in QUEST-RA were associated significantly with Gross Domestic Product (GDP) in different countries (120). These findings are consistent with extensive evidence that macro-economic variables provide significant explanation of variation in health outcomes among different nations. GDP predicts variation in overall mortality, infant mortality, and life expectancy (121-123) in different countries, as well as outcomes of specific diseases, such as 5-year survival of cancer in 22 European countries (124).

Data from QUEST-RA may contribute to improvements in quality in the 3 domains of structure, process and outcomes (Table I). The importance of structure is evident, as QUEST-RA is the first study to document that current RA inflammatory activity is associated with macro-economic variables such as GDP in different countries (120). The relation to process is apparent as patients have much poorer status in countries in which biologic agents are less available. The impact on outcomes can be seen in the correlations of clinical status with GDP in various countries, which has important implications for the efforts of rheumatologists to improve quality of care. It is emphasized again that patient questionnaire data, as well as joint count measures in the DAS, are not available in usual medical records, but are needed to recognize variation in patient status and quality of care in different countries.

## Discussion and future directions

The studies reviewed in this report are based on data concerning three topics that cannot be described accurately in patients with RA from most medical records in usual clinical care or from clinical trials. The data needed to describe prediction of premature mortality in patients with RA, differences in patient status over 15 years, and comparisons of clinical status in unselected patients in 22 countries in QUEST-RA, involve joint counts and patient questionnaire scores, which are not collected by most rheumatologists. The obser-

**Table VII.** Structure, process, and outcomes in the QUEST-RA study per country (35).

| | | | Structure | | Process | | | | | Outcomes | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Median values | | | Taking now (% of patients) | | Median values of outcomes | | |
| Country | # sites | # patients | GDP/PPP per capita | Education | ESR | SJC28 | DAS28 | Prednisone | Any biologic | HAQ | Pain | Patient global |
| Netherlands | 3 | 317 | 29.3 | 11.0 | 15.0 | 1.0 | 2.9 | 16.1 | 19.2 | 0.8 | 2.5 | 2.7 |
| Greece | 3 | 300 | 20.4 | 12.0 | 23.0 | 0.0 | 3.1 | 70.7 | 47.0 | 0.3 | 2.3 | 2.0 |
| Finland | 3 | 304 | 29.3 | 9.0 | 13.0 | 1.0 | 3.1 | 50.3 | 12.5 | 0.6 | 2.8 | 2.8 |
| USA | 3 | 301 | 39.5 | 13.0 | 14.0 | 2.0 | 3.2 | 60.8 | 27.9 | 0.6 | 3.2 | 2.6 |
| Denmark | 3 | 301 | 33.1 | 10.0 | 14.0 | 1.0 | 3.3 | 14.3 | 20.6 | 0.6 | 2.6 | 2.8 |
| Spain | 3 | 302 | 23.6 | 10.0 | 17.0 | 1.0 | 3.4 | 32.6 | 15.3 | 0.9 | 3.1 | 3.6 |
| France | 4 | 389 | 27.7 | 10.0 | 16.0 | 1.0 | 3.6 | 72.5 | 50.4 | 0.9 | 3.9 | 3.6 |
| Sweden | 3 | 260 | 28.2 | 10.0 | 19.0 | 2.0 | 3.6 | 40.2 | 25.5 | 0.9 | 3.3 | 3.3 |
| Ireland | 3 | 240 | 37.7 | 12.0 | 18.0 | 3.0 | 4.0 | 31.7 | 32.1 | 0.8 | 3.4 | 2.9 |
| Turkey | 3 | 309 | 7.5 | 5.0 | 30.0 | 0.0 | 4.1 | 57.3 | 5.8 | 0.9 | 4.2 | 4.6 |
| UK | 3 | 145 | 28.9 | 12.0 | 19.0 | 1.0 | 4.1 | 28.3 | 14.5 | 0.9 | 4.1 | 3.6 |
| Germany | 3 | 225 | 30.0 | 10.0 | 20.0 | 3.0 | 4.3 | 26.2 | 22.7 | 0.8 | 5.0 | 4.9 |
| Canada | 1 | 100 | 32.9 | 12.0 | 21.0 | 2.0 | 4.3 | 25.0 | 23.0 | 1.0 | 4.6 | 4.0 |
| Italy | 4 | 336 | 28.0 | 8.0 | 28.0 | 2.0 | 4.5 | 51.8 | 12.8 | 1.1 | 4.9 | 5.0 |
| Estonia | 3 | 168 | 15.2 | 12.0 | 24.0 | 4.0 | 4.7 | 42.4 | 0.7 | 1.1 | 4.3 | 4.8 |
| Latvia | 1 | 61 | 12.0 | 12.5 | 25.5 | 2.0 | 5.1 | 55.7 | 26.2 | 1.4 | 5.1 | 5.4 |
| Hungary | 3 | 153 | 15.5 | 12.0 | 26.0 | 5.0 | 5.2 | 53.0 | 19.0 | 1.4 | 5.2 | 5.1 |
| Poland | 7 | 642 | 12.5 | 12.0 | 31.0 | 6.0 | 5.3 | 57.8 | 6.1 | 1.4 | 5.0 | 4.8 |
| Lithuania | 2 | 300 | 13.0 | 13.0 | 29.0 | 3.0 | 5.6 | 83.1 | 9.0 | 1.4 | 5.2 | 5.3 |
| Argentina | 2 | 246 | 12.5 | 9.0 | 30.0 | 9.0 | 5.6 | 63.4 | 2.8 | 1.0 | 5.0 | 4.7 |
| Serbia | 1 | 100 | 4.9 | 8.0 | 28.0 | 6.0 | 6.1 | 54.0 | 0.0 | 1.6 | 5.1 | 5.3 |
| Total | 61 | 5499 | | 11.0 | 22.0 | 2.0 | 4.1 | 49.0 | 19.0 | 1.0 | 4.1 | 4.2 |

GDP: Gross Domestic Product; PPP: purchasing power parity; ESR: Erythrocyte sedimentation rate; SJC: Swollen joint count; DAS: Disease activity score; HAQ: Health assessment questionnaire.
Source: Sokka *et al*., *Ann Rheum Dis*. 2007 Apr 5; [Epub ahead of print] (35)

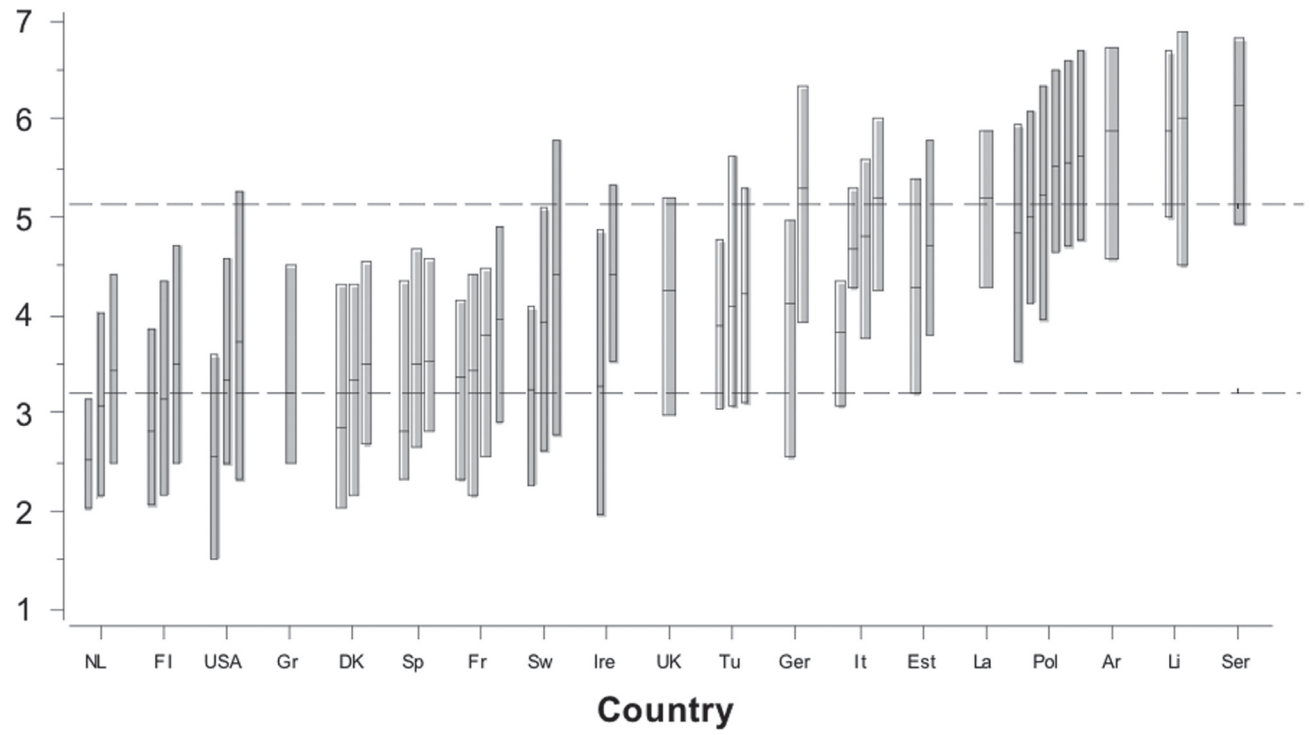


**Fig. 3.** Disease activity according to DAS28 [median, interquantile range (IQR)] in QUEST-RA per country and site. Reference lines indicate low (DAS28 ≤ 3.2) and high (DAS28 > 5.1) disease activity. Updated from Sokka *et al*., *Ann Rheum Dis*. 2007 Apr 5; [Epub ahead of print] (35), with permission.

vations may be viewed as an extension of the vision of Fries in the 1970s that standardized databases concerning patients with rheumatic diseases could enhance more rational care and improve patient outcomes (125, 126).

As a consequence of the absence of quantitative joint count and questionnaire data in usual medical records at this time, much activity concerning quality in RA, such as American College of Rheumatology (ACR) criteria for quality management of RA regarding treatment of patients with RA or monitoring of methotrexate therapy (28), are based on process measures. These measures are relevant to quality of care, but relatively weak surrogates for more direct and important measures of outcomes to assess quality.

Many clinicians have suggested that it is not possible to acquire patient data in standard rheumatology clinical care. Some of the complexities of performing a rigorous formal quantitative joint count in each patient are noted above. However, it is simple to collect a short patient questionnaire from each patient at each visit in the waiting room, as a component of the infrastructure of clinical rheumatology settings (110, 127). This procedure is easily implemented in any rheumatology clinical setting using the same questionnaire for each patient. Patient questionnaire data may be the best (and perhaps only) measure that can allow optimum analysis of quality management in RA (13), and patient questionnaires should be incorporated into standard rheumatology care (110, 127).

The QUEST-RA program represents an important accomplishment, but is limited thus far to a cross-sectional database concerning 100 patients at each site. It would be ideal if data compiled from QUEST-RA in this report would be available from longitudinal clinical databases in usual care, analogous to administrative databases from government sources. Although copies of the summary data were kept in the files of each patient who was included in QUEST-RA to be utilized in future patient care, it was recognized that custom-made software would allow a larger proportion (if not all) patients to be monitored for outcome measures. The goal of longitudinal data would require that patient questionnaire data be collected from each patient at each visit, and entered into a common, easily retrievable, but confidential, longitudinal database. Several sites in Northern European countries and in the United States have management systems for data from regular care, but these generally include only patients from one or few sites.

One further approach to extend QUEST-RA beyond a cross-sectional study is a software program called GoTreatIT, developed in Norway. This software provides a method to collect real-time data from each patient, assist clinical decision making and improve the quality of clinical care. GoTreatIT facilitates entry of two types of data into medical records in regular rheumatology care, from patient questionnaires completed by the patient and formal quantitative joint counts completed by the rheumatologist or assessor. GoTreatIT can collect patient-reported outcomes directly from the patient.

The patient is asked to arrive at the clinic 15 minutes prior to the scheduled visit to complete an expanded self-report health questionnaire on a touch screen. Data are stored in a central server. Patient self-report of clinical status is available for the health professional as calculated scores and as raw data, to scan ("eye-ball") before the patient enters the room and to facilitate a focused discussion. GoTreatIT also includes a homunculus for physicians to record a tender and swollen joint count. Data can be easily entered during the visit pointing each of the joints with positive findings on the screen, which provides immediate scores for disease activity on DAS28. Disease activity, patient-reported outcomes, and the use of DMARDs over time also are shown in time-oriented graphics.

GoTreatIT and other similar solutions could be used to improve the quality of rheumatology care, with data heretofore not available from the medical record, and to facilitate retrieval of this information. Even in offices in which joint count data from physicians and questionnaire data from patients regarding physical function, pain, global status and fatigue might be available, retrieval often requires review of inches-thick medical records. Even numerous screens of electronic medical records cannot depict patient status to assess accurately the quality of structure, process or outcomes without a data management system such as GoTreatIT or similar available programs.

The data in this review indicate the importance of data from joint counts and patient questionnaires in approaches to improve quality of care in RA patients, including analyses of premature mortality, changes in clinical status over 15 years, and the QUEST-RA database from 22 countries. Extensive data are now available that can be analyzed further to better understand structure (demographic, macro economic), process (clinical and treatment variables), and outcomes (mortality, functional, and work status), which may contribute to differences in quality of care for patients with RA in different countries. Recognition of major differences in outcomes can lead to more informed efforts to improve structure and process of care. The ultimate goal of these efforts is to improve outcomes for patients with RA in all countries.

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