
Quantitative measurement of patient status in the regular care of patients with rheumatic diseases over 25 years as a continuous quality improvement activity, rather than traditional research

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ABSTRACT

Patient assessment in rheumatology is characterized by an important paradox: many extensively-characterized quantitative measures and indices have been developed for rheumatoid arthritis (RA), psoriatic arthritis, systemic lupus erythematosus (SLE), ankylosing spondylitis, vasculitis, osteoarthritis, fibromyalgia, and other rheumatic diseases. However, most regular rheumatology care is guided largely by qualitative clinical impressions, without such measures or indices or any quantitative data other than laboratory tests to assess patient status and/or quality of care. This paradox may be explained in part by regarding the development of measures primarily as clinical research activities, while viewing the application of measurements in regular clinical care as continuous quality improvement (CQI) activities. The development of measures has emphasized validity and reliability, but generally ignored feasibility and acceptability to patients and health professionals, both of which are needed for application in regular clinical care.

A summary of the application of clinical measurement in patients with RA over 25 years between 1982 and 2007 at a weekly academic rheumatology clinic conducted by the senior author is presented as 20 often contemporaneous CQI cycles. These cycles include development of a user-friendly modified health assessment questionnaire (MHAQ); assessment of psychological status; monitoring of mortality outcomes; comparisons of joint counts, radiographic scores, and laboratory tests to the MHAQ; a 28-joint count; prospective study of the MHAQ to predict mortality when joint counts, radiographic scores, and laboratory

tests are available; development of a multidimensional HAQ (MDHAQ) with complex activities; a fatigue scale; a self-report joint count; scoring templates; a computerized data management system; flow sheets to monitor MDHAQ status; visual analog scales as 21 circles rather than 10 cm lines; composite RAPID3 (rheumatology assessment patient index data) scores for 3 patient measures; and defining RAPID categories for high, moderate and low severity, and near remission. The latter cycles remain under study as ongoing CQI activities.

Introduction

Quantitative assessment of patients with rheumatic diseases, whether to assess, monitor or document patient status, or to evaluate the quality of care, is characterized by an important paradox. Many extensively-characterized measures and pooled indices (1) have been developed over the last 25 years, since a seminal conference organized by Drs. Tugwell and Bombardier in 1982 (2, 3). Valid and reliable measures are available to assess rheumatoid arthritis (RA) (4-8), psoriatic arthritis (9, 10), systemic lupus erythematosus (SLE) (11-17), ankylosing spondylitis (18-23), vasculitis (24-28), osteoarthritis (29), fibromyalgia (30), pain (31-34), and fatigue (35-37), to cite only a few. Quantitative measures and indices have led to major progress in clinical trials and other clinical research in rheumatology.

The paradox is that fewer than 1% of patients seen in regular clinical care have been assessed using any of these excellent quantitative tools. Most regular rheumatology care is conducted according to qualitative "Gestalt" clinical impressions, without quantitative data. Therefore, any possible benefits

of major advances in the quantitative measurement of rheumatic diseases to guide decisions concerning therapy, document the possible effectiveness (or ineffectiveness) of these therapies, and/or assess quality are available for only a few patients seen in regular clinical care.

One perspective concerning this paradox may be to view development of measures of patient status in rheumatic diseases largely as a research agenda, versus application of measurement in regular clinical care as a continuous quality improvement (CQI) activity. Development of measures is based on rigorous methodologies, to identify optimal validity (Does the measure address what is thought to be measured?), reliability (Is the measure reproducible?), and measurement precision (2, 3). The measures often are long and not amenable to being reviewed or scored easily in a busy clinical care setting. Indeed, protocols of most clinical trials and many clinical research projects direct the investigator not to review the data. Therefore, quantitative measurement appears to add a burden to the patient and clinician, without apparent benefits for patient care.

By contrast, development and application of measurement in regular clinical care may be viewed as a CQI program, with attention focused not only on the validity and reliability of the measures, but also on their feasibility and acceptability to patients and health professionals (38-43). Sometimes less-er formal psychometric properties may be accepted, so that measurement is available for all patients within the infrastructure of regular care (42). For example, the classical 66/68 joint count for RA – with five graded scores for 5 criteria of swelling, tenderness, pain on motion, deformity and limited motion – was abbreviated to 28 joints scored “yes/no” for swelling and tenderness (44). Another example is modification of the health assessment questionnaire (HAQ) (45) to a multidimensional HAQ (MDHAQ) (46, 47), formatted so that it can be reviewed, scored, and available for clinical decisions in patients with all rheumatic diseases in busy clinical settings. Such simplifica-

tions illustrate that measures suited to regular care may differ substantially from measures designed for clinical trials and clinical research.

This essay summarizes results of efforts to apply clinical measurement in all patients with all rheumatic diseases at all visits to a weekly academic rheumatology clinic conducted by the senior author at Vanderbilt University over 25 years between 1982 and 2007 as a CQI agenda. These activities reflect an approach used intuitively prior to the formal application of CQI methods in clinical medicine (48, 49). New observations did emerge from some of these activities, which may be viewed as “research” findings, as described below. The focus is on the assessment of RA, the primary disease in rheumatology care, although the author has found the same approach, ultimately based on the value of the MDHAQ, to be useful in all patients with all rheumatic conditions (50).

Continuous quality improvement (CQI)

Continuous quality improvement (CQI) is an approach designed to advance the efficiency and safety of complex processes. It has contributed to success in many industries, but is only beginning to penetrate the medical world (48, 49). The traditional, formal CQI methodology involves a series of Plan-Do-Study-Act (PDSA) cycles to identify a problem, plan a solution, pilot-test the proposal, study its impact, and determine actions for the next cycle to promote further improvement and broader implementation (Fig. 1). CQI activities may parallel one another to analyze a new challenge, with a new PDSA cycle in the midst of an ongoing PDSA cycle. Ultimately, all activities should act in synergy to achieve the desired progress.

The CQI approach in medicine was given great impetus by the pioneering work of Berwick and colleagues (48, 49, 51), and has been identified by a variety of titles, including the “six sigma,” “quality improvement” and “total quality management” (52, 53). CQI has been introduced into rheumatology by reports of Harrington, Newman and

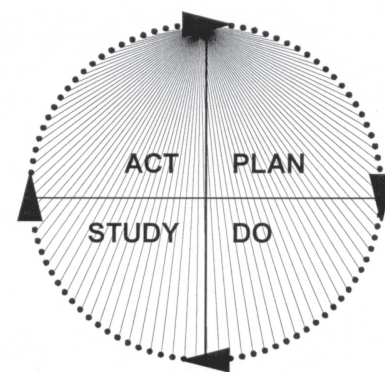


Fig. 1. The four-stage continuous quality improvement (CQI) cycle.

others (54-58). CQI is similar to formal scientific research in that each PDSA cycle involves a hypothesis/question and a methodological approach to test/observe the intervention proposed as a solution. However, CQI differs from traditional medical research in several important ways (Table I).

Some differences between CQI and traditional medical research – as well as the modern offshoots of traditional research, the randomized controlled clinical trial and practice guidelines – are summarized in Table I. Traditional medical research involves “reductionism” to isolate a single variable (such as a bacterium or toxin) and determine the effects of this variable, reporting conclusions that are regarded as valid until supplanted by new information. The clinical trial seeks to mimic laboratory research, again isolating a single test variable – the therapy – and keeping all other variables constant through randomization, with a report at the conclusion regarding the efficacy (or lack of efficacy) of the therapy. Development of practice guidelines introduces a modification of this procedure, with an effort to forge a consensus among experts based on the evidence in the medical literature (usually clinical trials) and expert opinion when “evidence” is not available, with a resulting document regarded as applicable to medical care until supplanted by new guidelines.

In contrast to traditional research and clinical trials, CQI seeks to take into account all patients rather than a cohort of selected patients, and involves implementation of the findings by the authors of the reports, which is not

Table I. Comparison of the methodologies of traditional medical research.

| Feature of method | Methods | | | |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|
| | Traditional research methodology | Clinical trials | Development of practice guidelines | Continuous quality improvement |
| Approach to problem | “Reductionist” approach – isolate a single variable | “Reductionist” approach – isolate therapy from other variables through randomization | “Delphic” approach to a consensus based on evidence and expert opinion | Include “real world” conditions – no effort to isolate variables |
| Result of process | Published report based on evidence to support a conclusion, and regarded as valid until new reports supplant this conclusion | Published report regarding the efficacy or lack of efficacy of a test therapy | Published guidelines, considered applicable to all patients with a particular diagnosis, and regarded as valid until new guidelines are developed | New strategies based on ongoing evaluation, regarded as amenable to continuous improvement through Plan-Do-Study-Act cycles |
| Patients included | None or very limited number | Limited number based on power calculations, and inclusion and exclusion criteria | Limited number included in the published evidence | All patients included |
| Underlying assumption | A scientific “truth” is established by laboratory experiment or other systematic methodology | Definitive data are available from trial results | It is possible to develop a series of guidelines based on the available evidence and expert opinion to improve medical care | The world is imperfect and all strategies are subject to doubt and open to continuous improvement based on actual observations |
| Responsibility of the author to implement the report’s results | None | None | Some | Required |
| Level of physician comfort with approach | High | High | Moderate | Low |

necessarily the case for the authors of traditional research reports. Other distinctive aspects of CQI include the potential brevity of a PDSA cycle; the possible need for hybrid methodologies; the localized and immediate use of findings; and a high perceived value of negative PDSA cycles. Perhaps most importantly, CQI conclusions are recognized as not necessarily definitive, but rather as requiring continuous reassessment toward further process improvement (59). CQI accepts the world as imperfect and without “final” answers, but with ongoing doubt that should stimulate continual reassessment and development of new strategies (59). The Type 2 translational research category recently developed to transfer research findings into practice shares some of the characteristics of the CQI approach (60).

Medical professionals generally are more comfortable with the definitive conclusions of laboratory research studies, clinical trials, or practice guidelines than with the uncertainty implicit in CQI. At the same time, physicians per-

form CQI much of the time, although this term has not been applied to a formal description of medical practice. Efforts to become a better physician involve constant self-assessment, with questions such as: What did I do today? How could I do my job better tomorrow? What can I do to be of more help to my patients? These questions are addressed informally by repeated PDSA cycles in daily patient care, such as the activities presented in this report to implement measurement in regular care. Indeed, the effective “practice” of medicine may be characterized as involving continual process improvement.

CQI may recognize the reality that most individual patients with rheumatic diseases can be treated in many different ways that are equally valid and supported by “evidence,” such as the choice of a biologic agent for a patient with RA or the frequency of laboratory monitoring of methotrexate therapy. Recognition of multiple options may be contrasted with the suggestion that “evidence-based” “best” approaches exist for most situations. “Best” ap-

proaches are rare in rheumatology, even when “evidence” is available, and often evidence is limited or entirely absent. A CQI philosophy can provide a more comfortable and effective quality movement in rheumatology. Rheumatologists could be leaders, held up as beacons of best practices within medicine, using CQI to improve the results of care and document process improvement and quality.

At the same time, like all methodologies CQI has its limitations. While some studies indicate improved care and outcomes for depression based on CQI programs in busy clinical settings (61, 62), other efforts have not revealed significant advantages to the CQI approach for the treatment of depression (63–65). A comprehensive effort by Minneapolis health maintenance organizations (HMOs) to improve preventive services through CQI had very limited success (66). Four possible explanations were considered by the authors to explain the failure of CQI in this study: (i) the clinics were atypical and resistant to intervention; (ii) measurement

Figure 2. Timeline of activities, 1980–2007.

| CQI activity | 1980 | 1985 | 1990 | 1995 | 2000 | 2005 |
|-----------------------------------------------------------------|------|------|------|------|------|------|
| 1 Questionnaire selection and usage | ■ | | | | | |
| 2 Modified HAQ - user friendly | ■ | ■ | | | | |
| 3 Assess psychological status | ■ | ■ | ■ | ■ | | |
| 4 9 year RA mortality outcomes | ■ | ■ | ■ | | | |
| 5 Assess each patient at each visit | ■ | ■ | ■ | | | |
| 6 MHAQ compared to HAQ | ■ | ■ | | | | |
| 7 Radiographic scoring vs other measures | ■ | ■ | ■ | | | |
| 8 Laboratory measures in assessment and prognosis | ■ | ■ | ■ | | | |
| 9 MHAQ compared to traditional measures | ■ | ■ | ■ | | | |
| 10 Reduced joint counts | ■ | ■ | ■ | | | |
| 11 MHAQ as predictor of 5-year mortality in new cohorts | ■ | ■ | ■ | ■ | | |
| 12 Flow sheets to monitor regular care | ■ | ■ | ■ | ■ | ■ | ■ |
| 13 MDHAQ to include complex activities and psychological status | ■ | ■ | ■ | ■ | ■ | ■ |
| 14 Scoring templates on MDHAQ | ■ | ■ | ■ | ■ | ■ | ■ |
| 15 Computerized data management system | ■ | ■ | ■ | ■ | ■ | ■ |
| 16 Visual analog scales as 21 circles rather than 10 cm lines | ■ | ■ | ■ | ■ | ■ | ■ |
| 17 Index of 3 patient measures – PAS or RAPID3 | ■ | ■ | ■ | ■ | ■ | ■ |
| 18 Self-report RADAI joint count on MDHAQ | ■ | ■ | ■ | ■ | ■ | ■ |
| 19 RAPID scores that include physician measures | ■ | ■ | ■ | ■ | ■ | ■ |
| 20 RAPID categories for high, mod, low severity, near remission | ■ | ■ | ■ | ■ | ■ | ■ |

Notes: HAQ = Health Assessment Questionnaire; MHAQ = modified HAQ; RAPID = Routine Assessment of Patient Index Data

Fig. 2. Timeline of activities, 1980–2007.

could have been inadequate – small incremental advances of CQI may not be detectable using standard statistical methodologies (67); (iii) delivery of the intervention may have been inadequate – the program was disseminated before sufficient PDSA pilot testing and the project coaches did not provide flexibility at individual practice sites; and (iv) CQI may have been “an inappropriate mechanism for making preventive services improvements” (66).

CQI may be viewed more as a general approach than as a formal structured methodology to improve quality in care, as noted above. There is, after all, considerably more uniqueness in activities over an 8-hour day in a medical clinic than in most industrial situations, in interactions with patients who have different diagnoses of varying severity. However, substantial stereotypic activity is seen as well – more than is generally recognized, particularly in the col-

lection of patient questionnaire data as a component of the infrastructure of care (68). As with traditional research, the successful application of CQI requires training, experience, and a receptive clinical environment.

The remainder of this essay presents an expansion of previous reviews (69, 70) concerning activities by the senior author over a 25-year period from 1982 to 2007 in the quantitative monitoring of every patient with any rheumatic disease at each visit to a weekly academic rheumatology clinic, as a CQI rather than a traditional research agenda, through 20 different CQI cycles (Fig. 2). The description of each cycle begins with a “question concerning the goal” that led to the Plan-Do-Study-Act activities. These cycles are interpreted less literally than in the usual CQI structure, viewing CQI as an approach to assess patients quantitatively, without necessarily meeting the PDSA methodology

rigorously in each cycle. These efforts have emphasized a number of pragmatic considerations:

- feasibility of the measures, leading to formulation of a reduced 28-joint count (71) and modified and multidimensional health assessment questionnaires [MHAQ (72) and MDHAQ (46, 47)] derived from the original HAQ, based on the criterion that major questionnaire information should be on a single side of one page, designed for easy completion by the patient and rapid review by the staff in a busy clinical setting (42);
- feasibility of questionnaire distribution, with the observation that the most successful method was for the office receptionist to distribute the same short questionnaire to each patient, irrespective of the diagnosis, at each visit upon registration in the clinic, rather than attempting to se-

lect patients according to diagnosis or visits (42, 68);

- usefulness of the measures to the rheumatologist in making clinical decisions, including comparisons of the joint counts, laboratory tests, radiographic scores and patient questionnaires (73);
- adding other measures to the MDHAQ physical function, pain, the patient estimate of global status, including a fatigue visual analog scale (VAS), recent medical history events (probably the most timesaving of all the new features), a symptoms checklist "review of systems," a listing of medications used, a patient self-report rheumatoid arthritis disease activity index (RADAI) joint count (74), and demographic data (39, 40, 50, 75);
- scoring templates for the MDHAQ, to facilitate further quantitative scoring in a busy clinical setting (76);
- incorporation of the scores into flow sheets which also include laboratory and medication data (40);
- a simple data management system (based on Access database software) to organize the data in regular care (40);
- an index of patient questionnaire measures, called a 'routine assessment of patient index data' (RAPID 3), facilitated by using templates on the MDHAQ, which is correlated significantly with the disease activity score DAS28 (40, 69);
- recognition of 4 categories of a RAPID3 index – near remission, low, moderate and high severity (75) – designed to help guide the rheumatologist in providing "tight control" of RA (77).

Over the years of the CQI process, a number of measures that were quite valid statistically were deleted from use in regular care on the basis of pragmatic considerations. Deletions included the 28-joint count (44), which was viewed as adding little to patient questionnaire data in regular care, particularly after a self-report joint count was added (74). Medication data were deleted when the hospital instituted a system that made collection on the MDHAQ unnecessary. Also deleted were many validated

self-report scales – such as scales to assess pain, change and satisfaction in activities of daily living on the MHAQ (72), a rheumatology attitudes index to assess helplessness in patients (78, 79), and other measures, after new scales were developed that were judged to be more informative than the previously included instruments. In contrast to a trend in research programs to add further measures without deleting earlier measures, a CQI approach may delete or replace a measure based on pragmatic considerations or experience, particularly in order to fit the most relevant information into a single-page patient questionnaire for completion in a busy clinical setting.

CQI Cycle 1: Patient questionnaires in regular rheumatology care

- *Question concerning goal:* Can patient questionnaires be used to assess patient status in regular clinical care?
- *Plan:* Ask patients to complete the health assessment questionnaire (HAQ) (45) or arthritis impact measurement scales (AIMS) (80), published in *Arthritis and Rheumatism* in 1980, to assess patient status in regular clinical care.
- *Do:* Include HAQ or AIMS at patient visits in regular care.
- *Study:* Patients accept questionnaires readily.
The self-administered format is as informative as questioning by a health professional.
The HAQ is more user-friendly than the AIMS.
- *Act:* Patients accept and many welcome a questionnaire, when the rheumatologist examines the results.
The self-administered instrument is accepted, resulting in more efficient use of both the patients' and the health professionals' time.
The HAQ is more user-friendly – use HAQ in all patients and discontinue using AIMS.

CQI Cycle 2: Modified HAQ (MHAQ) – user-friendly for patients and simple to score for health professionals involved in regular care.

- *Question concerning goal:* What is

the best format for a patient questionnaire in regular care?

- *Plan:* Reduction of the HAQ – consisting of 20 activities in 8 categories (2 or 3 activities in each category) printed on two sides of a page – to a modified HAQ (MHAQ) with 8 activities (one in each category from the HAQ), printed on one side of one page and designed for rapid review by the clinician (72). Include only activities performed daily by all patients, chosen from each of the 8 categories.
- *Do:* Various formats of the HAQ with a reduced number of activities were distributed and completed by patients on different clinic days.
The MHAQ with 8 activities, one from each HAQ category, chosen on the basis of the likelihood that all patients would perform that activity each day (eliminating "shampoo your hair," "run errands," as not performed by all patients), was found to be optimal.
In a validation study, half of the patients were given the HAQ for completion when they arrived for their visit, and were asked to complete the MHAQ at the end of their visit. The other half completed the MHAQ at the beginning and the HAQ at the conclusion of their visit.
- *Study:* Patients find the format of the MHAQ preferable to the HAQ.
The MHAQ is more easily reviewed ("eyeballed") by the clinician than the HAQ.
A formal comparison of HAQ versus MHAQ demonstrated the validity of the MHAQ, as it captures most of the information found on the 20-item HAQ (72).
MHAQ scores are systematically about 0.3 units lower than HAQ scores, due to the simpler activities selected for the MHAQ (46).
- *Act:* Distribute MHAQ at all visits to all patients with all diagnoses.

CQI Cycle 3: Assess psychological status in patients with RA

- *Question concerning goal:* Can a patient questionnaire for regular care include a measure of psychological status?

- *Plan:* Develop an index to be included on the questionnaire for regular care, based on the construct of "learned helplessness" (81, 82).
- *Do:* Helplessness index included on all versions of the MDHAQ from 1981-1994. Helplessness index reduced from 15 to 5 items. Name changed as both patients and staff found the term "helplessness" unwelcome.
- *Study:* The "arthritis helplessness index" is a valid and reliable 15-item questionnaire, which is readily completed by patients and informative to health professionals (78). The index was later termed the "rheumatology attitudes index," with 5 items giving similar information to the 15 items (83). The helplessness index predicts mortality over long periods, and explains in part associations of formal education and mortality in patients with RA (84).
- *Act:* Helplessness was assessed in the clinic. Over the years, however, the information was found to be redundant with the MHAQ and ultimately was included as a research questionnaire, but not in regular care.

CQI Cycle 4: Mortality outcomes of RA over 9 years from 1973-1982

- *Question concerning goal:* What are the outcomes of RA patients 9 years after an extensive quantitative baseline evaluation in 1973?
- *Plan:* Systematic review in 1982 of 75 patients with RA who had been assessed according to an extensive quantitative baseline evaluation in 1973 that included joint counts and 80 questions concerning functional status.
- *Do:* Account for all 75 patients, including 55 alive and 20 dead. Analyze potential predictors of 9-year outcomes.
- *Study:* Severe functional declines seen in most patients over 9 years (85). Increased mortality rates seen, with shortened lifespan by 8-12 years (85). Patient responses concerning functional status in activities of daily liv-

ing provide a significant predictor of mortality over 9 years (72, 85-87). Formal education level is another significant predictor of mortality (88).

- *Act:* Patient questionnaires are no longer optional in regular care, but appear to be "required" to assess all patients with RA.

CQI Cycle 5: Assess each patient at each visit using the same MHAQ

- *Question concerning goal:* What is the best strategy to adopt, in order to have patients complete a questionnaire in regular care?
- *Plan:* Assess every patient with some version of a patient questionnaire.
- *Do:* Clinic receptionists were instructed to ask each patient to complete a questionnaire upon registration at the clinic. It was found most feasible to present the same questionnaire to all patients.
- *Study:* The best strategy in regular care to have all RA patients complete the MHAQ is to ask every patient – not only those with RA – to complete the same questionnaire in the waiting area when they register for a visit, as part of the infrastructure of care (38, 68). MDHAQ is useful in all patients with any rheumatic disease (50).

- *Act:* Assess all patients with all diagnoses at all visits according to same MHAQ.

CQI Cycle 6: MHAQ compared to traditional measures of clinical status in RA – joint count, radiographs, laboratory tests.

- *Question concerning goal:* Are MHAQ scores correlated significantly with traditional measures of status in RA, including joint counts, radiographs, and laboratory tests?
- *Plan:* Conduct extensive baseline review, from 1984–1986, of 210 patients with RA, including MHAQ, joint counts, quantitative radiographic scores and laboratory measures.
- *Do:* Perform an extensive baseline evaluation [eventually called the "Standard Protocol to Evaluate

Rheumatoid Arthritis" (SPERA) (89)], which includes a quantitative questionnaire, joint count, radiographic score and laboratory tests, in 210 patients with RA.

- *Study:* Patient questionnaires are correlated significantly with traditional RA measures, i.e. the joint count, radiographic score, and laboratory tests (73).

Questionnaires are more highly correlated with joint counts than with the radiograph and laboratory tests, which are more highly correlated with one another (73, 90, 91).

- *Act:* Reinforce the value of a patient questionnaire at each visit as a primary quantitative measure of status in patients with RA.

CQI Cycle 7: Radiographic scores in RA: early damage and comparison with other measures.

- *Question concerning goal:* How much does radiographic scoring contribute to the regular care of patients with RA, in addition to other measures?
- *Plan:* Analyze the modified Sharp radiographic scores in 210 patients with RA using the database established in cycle 6 for comparisons of the radiographs to questionnaires, joint counts, and laboratory measures.

- *Do:* Score the radiographs. Analyze radiographic changes over time.

Compare radiographic changes to other measures of clinical status in the cross-sectional RA database of 210 patients.

- *Study:* Radiographic damage begins in most patients during first 2 years of disease (92).

The radiographic score is correlated with other measures in patients with RA, but more strongly with laboratory tests than with patient questionnaire measures (73, 90, 91).

Radiographs add relatively little, compared to patient questionnaires, to explain or predict disability, premature mortality and the costs of RA over 5 years (93).

Compare the Larsen and Sharp scores in the same radiographs –

similar results (43, 94).

- *Act:* Continue to analyze radiographs over time, with observations that they are far less explanatory of work disability, premature mortality and costs compared to patient questionnaires.

CQI Cycle 8: Laboratory measures in the assessment and prognosis of RA

- *Question concerning goal:* How much do laboratory tests add to the assessment, management, and prognosis of patients with RA in regular care?
- *Plan:* Compare the results of the erythrocyte sedimentation rate (ESR), rheumatoid factor (RF) and HLA haplotype tests to other measures of clinical status, including patient questionnaires, radiographs, and joint counts in the database of 210 RA patients in regular care established in cycle 6.
- *Do:* Perform analyses
- *Study:* ESR is correlated significantly with functional status and joint swelling (73).
RF and HLA type are only weakly correlated with functional status and joint swelling (90).
ESR, RF and HLA type are correlated far more strongly with radiographic scores than with functional status scores on a patient questionnaire (73, 90).
Laboratory measures are correlated significantly with other measures in patients with RA (73, 90), more strongly with radiographs than with patient questionnaire measures (90). Include C-reactive protein (CRP) after 1995, with evidence that 40% of patients with RA have normal ESR or CRP at presentation, 25% have both normal ESR and CRP, and 15% have normal ESR, CRP and RF (95).
Laboratory tests found to be far less explanatory of work disability, costs, and premature mortality than patient questionnaires (93).
Laboratory tests add relatively little information to patient management.
- *Act:* Continue to analyze laboratory values over time to confirm or refute the above.

CQI Cycle 9: Reduced joint counts for patients with RA

- *Question concerning goal:* Can reduced joint counts, which are more easily assessed in regular care than the standard 68-joint count, be as informative as the standard 68-joint count?
- *Plan:* Use the database of 210 RA patients established in cycle 6 to analyze the standard 68-joint count and other joint counts consisting of 42, 36 or 28 joints (based on different joints in each count) in comparison with other measures of clinical status, including patient questionnaires, radiographs, and laboratory tests.
- *Do:* Analyses of the 42-, 36- and 28-joint counts compared to other measures of clinical status in the 210 patients in the clinical cross-sectional RA database.
Later analyses of clinical trials to compare the results according to a 28-joint count versus the standard 68-joint count.
- *Study:* A 28-joint count is as informative as a standard 68-joint count in a database established in standard clinical care (44).
A 28-joint count is as informative as a standard 68-joint count in clinical trials (71).
- *Act:* Perform a 28-joint count in all visits of patients with RA, 1988-1994.
A formal, quantitative joint count was found to add little information when quantitative data from the MHAQ, pain, and global scores were available, particularly with the addition of a self-report joint count in cycle 18, as a careful, qualitative joint examination appeared to be adequate.
The formal quantitative joint count was gradually replaced by a qualitative joint examination and a self-report joint count in regular care; the formal quantitative joint count was used only in research studies.

CQI Cycle 10: MHAQ as a predictor of 5-year mortality in new RA cohorts

- *Question concerning goal:* Can the MHAQ serve as a prospective predictor of premature death in new

cohorts of RA patients, as described in retrospective analyses of prospectively-collected data in an earlier RA cohort in cycle 4?

- *Plan:* Establish new cohorts of patients with RA from two sources: 210 patients in Nashville who also had assessments of their joint count, radiographic scores and laboratory measures, described in Cycle 6. 1,497 additional patients of 15 private practice rheumatologists in different US states, for whom only questionnaire data were available.
- *Do:* Assess 5-year survival according to the MHAQ and other available measures, as possible confounding variables to predict mortality in these two cohorts.
- *Study:* Three significant independent predictors of 5-year mortality in the Nashville cohort of 210 RA patients were MHAQ, age and co-morbidities (93).
Significant predictors of mortality in the cohort of 1,497 patients from 15 private practices were MHAQ, education level and helplessness scores (84, 96).
- *Act:* Continue to regard MHAQ as the most valuable available measure for the regular care of patients with RA and other rheumatic diseases.

CQI Cycle 11: Flow sheets to monitor regular clinical care

- *Question concerning goal:* How can the capacity of the MHAQ to support decision-making by the rheumatologist be optimized?
- *Plan:* Develop flow sheets that include 3 types of data: patient questionnaire scores, laboratory tests and medications.
Early versions also included joint count data, which were eliminated when routine performance of the 28-joint count was discontinued.
- *Do:* Flow sheets were completed for all patients using a "pencil and paper" format, with questionnaire scores available for comparison to previous visits prior to seeing the patient.
- *Study:* A flow sheet appears to improve clinical decision-making (40).
A flow sheet saves considerable time

for the rheumatologist (39, 40).

- *Act:* Flow sheets with questionnaire data are completed for each patient at each visit, before the rheumatologist sees the patient, to compare present status with status at previous visits.

CQI Cycle 12: Multidimensional HAQ (MDHAQ) to include complex activities and psychological status

- *Questions concerning goal:* Can the user-friendly HAQ format with 4 response items for patients be expanded to include complex activities, to better reflect the status of patients with RA in the 1990s compared to earlier periods, to reduce scoring differences between the HAQ and MHAQ, and also to include psychological status in a MDHAQ?
- *Plan:* Add 6 complex activities to the 8 activities on the MHAQ, as well as 4 psychological items from the standard HAQ format with 4 response options, fitting all the items on one side of one page.
- *Do:* All patients completed an MDHAQ in the new format with additional activities and psychological items at each visit over 3 years (1995–1998).
- *Study:* The addition of complex activities to the MDHAQ diminishes the “floor effects” gap of 0.3 units between the HAQ and MHAQ (46). Psychological items are informative in the simple questionnaire format; correlation of the depression item with the Beck depression inventory was $\rho = 0.6$ ($p < 0.01$) (46). Later it was found that the inclusion of only two complex activities – “Can you walk 2 miles or 3 km” and “Can you participate in recreation and sports as you would like” – for a total of 10 activities, performs as well as 14 activities (47).
- *Act:* Use the MDHAQ with complex activities and psychological items in regular care. Retain 3 psychological items for anxiety, depression and sleep, as being informative to the clinician reviewing the questionnaire, but do not include these in the formal MDHAQ score.

CQI Cycle 13: Scoring templates on the MDHAQ

- *Question concerning goal:* Can provision of scoring templates directly on the MDHAQ save time for a health professional in scoring the questionnaire prior to seeing the patient?
- *Plan:* Include scoring templates designed for a health professional to convert a 0–30 physical function scale (score based on 10 responses of 0–3) to a total score of 0–10; add to the questionnaire boxes to record scores for physical function, pain, and global status.
- *Do:* Enter scores on the questionnaire and flow sheet, which may appear redundant, to determine if this procedure is useful to the rheumatologist in patient care.
- *Study:* A scoring template is helpful in calculating a score for patient assessment prior to seeing the patient (40).
- *Act:* Scoring templates are included on all subsequent versions of the MDHAQ, including templates for RAPID indices (as discussed in cycles 14 and 18).

CQI Cycle 14: A computerized data management system for patient data in regular care

- *Question concerning goal:* Can a practical computer database management system be developed to monitor patients longitudinally in a busy clinical setting?
- *Plan:* Develop an ACCESS database based on a format of pen and paper flow sheets, with one page to incorporate 7 visits over time, and comprising 3 types of data: patient questionnaire scores, laboratory tests, and medications.
- *Do:* Prepare computerized flow sheets for the next visit while completing correspondence for the present visit, based on data entry requiring 2–5 minutes per patient, entered by a student or secretary.
- *Study:* Substantial changes in the clinical status of all RA patients seen in 2000 versus 1985 could be documented using the computerized database (97). The rarity of problems with meth-

otrexate in regular clinical care could also be documented (98).

Maintenance of improvement over periods of 5 years in regular clinical care could be documented (99).

- *Act:* Continue to use the ACCESS program to monitor patient care; develop a web-based entry system that will allow any rheumatologist to use this system.

CQI Cycle 15: Compare patients in clinical care versus clinical trials

- *Question concerning goal:* Do inclusion and exclusion criteria leave only a minority of patients seen in regular clinical care eligible for contemporary clinical trials?
- *Plan:* Assess whether and how many patients from regular care meet the inclusion criteria for clinical trials of biological agents.
- *Do:* Compare the number of swollen joints, tender joints, ESR, methotrexate use, and morning stiffness in patients seen in regular care in 2000 versus inclusion criteria for clinical trials of biological agents.
- *Study:* Most patients seen in regular care do not meet inclusion criteria for contemporary RA clinical trials (100, 101).
- *Act:* Advocate less stringent inclusion criteria for RA clinical trials.

CQI Cycle 16: Visual analog scales as 21 circles rather than 10-cm lines

- *Question concerning goal:* Can depiction of visual analog scales (VAS) for pain and global status as 21 circles, rather than as the classical 10-cm line, facilitate completion of a questionnaire by the patient and scoring by the rheumatologist in regular clinical care?
- *Plan:* MDHAQ versions were developed with pain and global VAS in a format consisting of 21 numbered circles, as well as additional formats with intermittent numbers under certain circles or different symbols (such as squares) to facilitate scoring of the VAS.
- *Do:* Distribute the MDHAQ with the new pain and global VAS formats at registration, and a second MDHAQ with a traditional 10-cm

line at the conclusion of the visit to one half of the patients. The remaining half receive an MDHAQ with a traditional VAS at the beginning of the visit, and a questionnaire with the new format at the conclusion of the visit.

- *Study:* Patients are comfortable with the multiple-circle VAS. Results are similar with the new VAS formats compared to the standard 10-cm line (102). Formats that rely on numbering only certain circles or on the use of different symbols (to facilitate scoring) lead patients to indicate specific values more frequently than would be expected, resulting in unacceptable "clustering" of responses (102). An optimal format is a 21-circle VAS, with all circles identical (102).
- *Act:* Introduce 21-circle VAS, with each circle numbered, into all subsequent versions of the MDHAQ.

CQI Cycle 17: An index of 3 patient measures from the RA Core Data Set – the PAS or RAPID3

- *Question concerning goal:* Can an index of the three patient self-report measures in the RA core data set – i.e., physical function, pain and global status, termed the patient activity score (PAS) or routine assessment of patient index data (RAPID3) score – be informative to a clinician in regular clinical care?
- *Plan:* Analyze the capacity of PAS or RAPID3 to distinguish active from control treatment in RA clinical trials compared to the ACR and disease activity score (DAS) criteria. Analyze correlations of PAS or RAPID3 with DAS in clinical trials and in patients seen in regular clinical care.
- *Do:* Analyze the clinical database to determine whether PAS or RAPID3 is correlated significantly with DAS. Analyze clinical trials involving methotrexate, leflunomide, adalimumab and abatacept to evaluate the capacity of PAS/RAPID3 to distinguish active from control treatments in a range similar to the ACR and DAS criteria.

- *Study:* An index of only 3 patient measures can distinguish active from control treatments in clinical trials in the range of ACR and DAS improvement criteria (103-105).

An index of the 3 patient measures is correlated significantly with DAS in regular clinical care (106) and in clinical trials (103-105).

- *Act:* Add RAPID3 scoring to the templates on the MDHAQ, with all 3 variables scored 0–10. Score RAPID3 routinely in regular care.

CQI Cycle 18: A self-report RADAI joint count on the MDHAQ

- *Question concerning goal:* Can a self-report joint count be included in a MDHAQ as informative to the clinician/rheumatologist?
- *Plan:* A rheumatoid arthritis disease activity index (RADAI) self-report joint count available from the literature (74) was added to versions of the MDHAQ for regular clinical care.
- *Do:* All patients completed the standard RADAI self-report joint count as part of a MDHAQ with no difficulties.
- *Study:* Qualitative RADAI self-report joint count scores help the clinician to detect patterns of joint involvement, but quantitative RADAI scores do not substantially increase the value to the clinician of MDHAQ scores (107). Scores on the RADAI self-report joint count do not add increased statistical significance to MDHAQ scores versus other measures (107). Nonetheless, a RADAI self-report joint count is useful to the rheumatologist engaged in regular patient care.
- *Act:* RADAI self-report joint counts, and scoring templates to convert raw 0–48 scores to 0–10, were added to subsequent versions of the MDHAQ. Clinical information from the RADAI is quite useful in patient care. However, experience over time suggests that formal scoring is not necessary, although it may be incorporated by some clinicians.

CQI Cycle 19: RAPID scores that include self-report or physician measures

- *Question concerning goal:* Does the addition of a joint count either by self-report or by a physician/assessor, and/or a physician global estimate, add to the capacity of RAPID3 to depict patient status?
- *Plan:* Evaluate 300 patients in regular care according to a SPERA review, and compare the scores for RAPID3 (physical function, pain, global status), to RAPID4 (the number signifies the number of variables in the index) which adds a joint count (patient self-report or physician-generated), and to RAPID5 which adds to RAPID4 a physician global assessment. Review clinical trials to analyze whether meaningful differences are seen between the results using RAPID3, RAPID4 or RAPID5.
- *Do:* 300 patients were assessed according to the SPERA protocol. RAPID3, RAPID4 and RAPID5 were computed on patients seen in regular care. Two abatacept trials, AIM and AT-TAIN, were analyzed using RAPID3, RAPID4 and RAPID5, although self-report joint counts data are not available in the clinical trial database.
- *Study:* RAPID3, RAPID4 and RAPID5 yield similar results in regular care (40, 41) and in abatacept clinical trials (108). A joint count and/or physician global estimate in a RAPID4 or RAPID5 does not add important information to RAPID3 in a database from regular clinical care (70).
- *Act:* Highlight RAPID3 as the most easily scored index, which appears to be as informative as RAPID4 with its added joint count and RAPID5 with its added joint count and physician global estimate. However, RAPID4 and RAPID5 are available for rheumatologists who feel that the additional information could prove useful. Continue to include a self-report joint count in the MDHAQ, but formal scoring of RAPID3 not in-

cluding the joint count, appears adequate.

CQI Cycle 20: Criteria for high, moderate and low severity, and near-remission, using RAPID scores

- *Question concerning goal:* Can criteria be identified to classify patients according to RAPID scores as having high, moderate or low severity, or near remission status, analogous to four categories in the DAS and clinical disease activity index (CDAI)?
- *Plan:* Classify patients in the clinical database and in the clinical trial database according to the RAPID scores and the cut points in the DAS.
- *Do:* Analyze patients according to RAPID cut points of 4, 2, 1 and 0, as well as according to 5, 2, 1 and 0, to designate high, moderate and low severity and near remission in the clinical database of 300 patients. Perform similar data analyses at the conclusion of the AIM and ATTAIN clinical trials.
- *Study:* One can classify patients as having high, moderate or low severity or near remission based solely on the patient self-report data in RAPID3 (70).

Classification is not improved substantially with data from the RAPID4 or RAPID5 for categories of disease severity (70).

- *Act:* RAPID3 scores provide guidelines for rheumatologists:
If > 4, strong indication to change therapy.
If > 2, moderate indication to change therapy.
If < 2, change in therapy generally not needed, particularly if < 1.

Conclusion

This essay has presented a summary of the quantitative clinical assessment of patients with rheumatic diseases seen in one patient care setting over a period of 25 years, an endeavor that is presented as a series of 20 quality improvement cycles rather than a research agenda. This perspective is presented in an effort to understand a curious paradox – that major advances

in the quantitative assessment of rheumatic diseases have been seen over the last two decades, but most regular patient care remains conducted without any quantitative clinical measurement other than laboratory tests, which often are not informative.

The focus has been on RA, the major disease seen in rheumatology care, although the principles appear to be applicable to all rheumatic diseases. These cycles have emphasized pragmatic considerations such as the feasibility of different types of measurements and distribution of patient questionnaires; use of scoring templates, flow sheets, and a data management system; replacement of joint count evaluations by a health professional with a patient self-report joint count; an index of patient questionnaire scores; and classification of patients as having high, moderate or low severity, or near remission of their RA, as a means of guiding “tight control” of clinical activity. The twenty cycles are presented within a formal Plan-Do-Study-Act CQI framework, although they may be interpreted less literally than the usual CQI analysis, viewing continuous quality improvement as an approach rather than a formal methodology.

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