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Mission Statement

The mission of the CRAJ is to encourage discourse among the Canadian Rheumatology community for the exchange of opinions and information.
What is a Rheumatologist?

What is a rheumatologist, and what do we do best? Certainly we all know what we do. We are the arthritis specialists; we look after patients with diseases of the joints, muscles, bones and immune system. But does the general population know what we do? Perhaps more important, do other physicians know what we do best? Judging from the referrals that I receive, I would say “no.” The patient with new-onset inflammatory disease often is not referred until late in the course of the disease—and yet I have a deluge of consultations for chronic pain syndrome, whiplash injury, post-trauma disorders and fibromyalgia.

There are approximately 300 rheumatologists in this country at present. Our forefathers in the field suggested that we need one rheumatologist for every 100,000 people. Some interested in this area feel a more accurate estimate is one rheumatologist for every 70,000 people, given the present complexity of treatment regimens and demands of academic programs.

We know there are presently 26 academic positions open in rheumatology in this country and many more community positions to be filled. We are not training adequate numbers of rheumatologists—even to replace our losses. We are not training clinician scientists or basic scientists in this field, as pointed out in this issue’s interview with Jean-Pierre Pelletier. And even if we begin today to increase the number of training positions, we are not going to have skilled clinicians or scientists for the next decade.

The problem goes further still. We are not turning on medical students to rheumatology, as evidenced by the vacant rheumatology positions across this country. No wonder people—even other doctors—don’t always understand what we do.

So how can we—300 Canadian rheumatologists—make improvements to this situation?

Things are not as impossible as they might seem. For the first time in decades, we have new, effective therapies that allow us to make a difference to patients with rheumatoid arthritis and other systemic inflammatory diseases. We can now treat osteoporosis. And there is active, exciting research being performed in this country in inflammatory disease, connective-tissue diseases, osteoarthritis and osteoporosis.

Perhaps we could use this wave of enthusiasm to encourage medical students and residents to enter our field? With the arrival of new medications, there is greater funding from pharmaceutical companies. These funds can be used to create programs for students and residents in rheumatology and used in continuing medical education. We can make a loud noise politically to help us obtain further government resources that can be put towards management of arthritis research and training programs.

It is my opinion that, as Canadian rheumatologists, we need to make others aware of what we do best and concentrate our efforts in those areas. We all know this is a rewarding and challenging specialty. We must encourage young students toward a career in rheumatology, either clinical or academic. We must work toward improving the compensation for our services in order to retain our present members.

This is going to be our challenge over the next three to five years.

In September you will receive a Needs Assessment for the CRA from Drs. Glen Thompson and Denis Choquette. Your input is critical in order to develop plans for the future of the CRA.

Thank you,

Dianne P. Mosher

Dianne P. Mosher, MD, FRCPC
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Instruments that evaluate health status, functional status, disability and quality of life (QoL) in adults with rheumatoid arthritis (RA) are prominent in recent literature, and their inclusion as outcome measures in clinical trials now is mandated by regulatory agencies, such as the FDA. Such measures also have been developed for the assessment of children with juvenile idiopathic arthritis (JIA). One of these measures has been included in the core set of six outcome measures for clinical trials (as decided by the Pediatric Rheumatology Collaborative Study Group [PRCSG] and the Paediatric Rheumatology International Trials Organization [PRINTO]). The inclusion of a functional measure for children represents an important milestone for rheumatology in Canada.

Functional status, health status and QoL, as referenced in the medical literature, frequently are used interchangeably, and thus may not have distinct meaning.1 “Functional status” is a broad summary phrase used to explain the effect of a disease on one’s ability to carry out usual tasks.

“Health status” refers to an overall point estimate of a person’s well-being in physical, psychological and social terms compared to baseline.

The “QoL” measurement includes both health status and functional status, and should attempt to incorporate some aspect of the patient’s own perception of those particular aspects of life that have been affected significantly and the extent to which these are influenced by the disease.1 In this context, one is attempting to measure health-related quality of life (HRQoL). Indeed, it seems that individuals, including children, are capable of distinguishing between health status, QoL and HRQoL,2 although this has been questioned.3

HRQoL may be generic or disease-specific, with the latter having greater applicability for clinical trials because of its greater sensitivity in the detection of important clinical change (responsiveness). Various groups have attempted to develop the definitive measure for application in children with JIA.

The ideal instrument should be practical and easy to use, should be capable of completion by the parents and/or child within a short time, and should measure physical function. The ideal instrument also should measure psychological function and social function, including school, family and behaviour issues, and should include a measurement of pain. It also should be reliable, valid and responsive. Such an instrument also should be appropriate for use in different countries, and hence different cultures, and thus must undergo translation as well as other important changes to ensure adaptability to the particular setting in which it ultimately will be used. Thus, international use of these measures presents an important challenge.4,5

None of the measures to be discussed in this article fulfills all of the above criteria. Nonetheless, important strides have been made. The following instruments are reviewed in detail elsewhere;5,6 below, they will be discussed in brief.
DISEASE-SPECIFIC INSTRUMENTS—MEASURES OF PHYSICAL FUNCTION

The Childhood Arthritis Impact Measurement Scales (CHAIMS). The CHAIMS was the first disease-specific measure developed for JIA. This instrument was a modification of the AIMS. The measurement properties of this instrument are not particularly good, however (except for the pain dimension, which showed good reliability and convergent validity). This was due mainly to the fact that most items do not apply to children under six years of age. Also, the face validity, content validity and responsiveness of CHAIMS have not been demonstrated, so this instrument is not in current use.

The Childhood Health Assessment Questionnaire (CHAQ). The CHAQ—which was derived from the adult HAQ—comprises two indices: Disability and Discomfort. The Disability Index assesses function in eight areas (dressing and grooming, arising, eating, walking, hygiene, reach, grip and activities), distributed among a total of 30 items. Each question is rated on a four-point scale of difficulty in performance, scored from 0-3. The question with the highest score determines the score for that functional area. If aids or devices are used, or assistance is required, the minimum score for that functional area is 2. The Disability Index is calculated as the mean of the eight functional areas. Discomfort is determined by the presence of pain, measured by a 100-mm visual analogue scale (VAS), extrapolated to a score of 0-3. In addition, a 100-mm VAS measures patient/parent global assessment of arthritis.

The CHAQ has excellent reliability and validity. While data from a small controlled trial suggest that the CHAQ is responsive, further work is needed in larger trials to clearly establish its responsiveness, and to determine its true value for use in efficacy trials.

The JAFAR has excellent reliability and validity. While data from a small controlled trial suggest that the JAFAR is responsive, further work is needed in larger trials to clearly establish its responsiveness, and to determine its true value for use in efficacy trials.

The Juvenile Arthritis Functional Assessment Report (JAFAR). The JAFAR was derived from the AIMS, the HAQ and the McMaster Health Index Questionnaire. JAFAR comprises one dimension and contains 23 items that assess ability to perform physical tasks in children older than seven years of age on a three-point scale scored from 0-2. The overall score range is 0-46, with lower scores indicating better function. Two separate versions are available, one for the child (JAFAR-C) and one for the parents (JAFAR-P).

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longitudinal follow up of a majority of children with chronic arthritis, although it offers little beyond the CHAQ.

**The Juvenile Arthritis Self-Report Index (JASI).**
The JASI was developed with a specific focus on physical activity in children over eight years of age with JIA.10 The emphasis of JASI is on responsiveness, and it is aimed primarily at rehabilitation interventions. The JASI contains 100 items, distributed among five categories of physical function (self-care, domestic, mobility, school, and extracurricular). Scores range from 0 to 100, with higher scores indicating better function. A seven-point Likert scale of difficulty in performing tasks is included. As a secondary component (JASI Part II), patients identify up to five tasks that are most problematic, and these tasks are evaluated on sequential follow up. This maneuver makes this component of the JASI potentially more responsive and patient-specific.

The JASI has been developed in a meticulous fashion, resulting in excellent reliability and validity. Its greatest drawback is the fact that it cannot be administered to children under eight years of age, and this prohibits its use in children with early-onset JIA. Also, because it is comprehensive, the JASI takes a long time to complete (45 minutes), which may make it less attractive for clinical use.

The JASI is, nonetheless, a comprehensive instrument with excellent measurement properties, whose greatest value probably is as a research tool for longitudinal studies.

**DISEASE-SPECIFIC INSTRUMENTS—QUALITY OF LIFE MEASURES**

**The Juvenile Arthritis Quality of Life Questionnaire (JAQQ).** The JAQQ measures physical and psychosocial function; it incorporates patient-specific data and is focused on the disease (and, thus, on measures of HRQoL).11 The JAQQ is applicable to all age groups and chronic-arthritis subtypes, and can be self-administered within a brief period of time.

The JAQQ comprises 74 items distributed among four dimensions: gross motor function (17 items), fine motor function (16 items), psychosocial function (22 items) and general symptoms (19 items). Each item is scored from 1 to 7 (“none of the time” to “all of the time,” based on how often the particular item is a problem for the child), with 7 indicating worst function. While respondents score all items on each occasion, the patient’s score is computed as the mean of the five highest scoring items in each dimension. The total JAQQ score is computed as the mean of the four dimensions. A pain scale is included but scored separately. English, French and Dutch versions are available.

The JAQQ has been developed in a detailed fashion, resulting in excellent validity and responsiveness, and, because of this, it might be the ideal instrument for clinical trials.

**The Childhood Arthritis Health Profile (CAHP).**
This instrument was developed to capture the broad range of health states in children with JIA, including physical functioning, psychosocial functioning and family impact of disease.12 The CAHP was developed in parallel with a generic instrument, the Childhood Health Questionnaire (CHQ).13 There is a parent-reported version as well as a teen-reported version for adolescents (13+ years of age).

The CAHP is self-administered and consists of three modules: generic health status measured by the CHQ, JIA-specific scales and patient characteristics. The initial report focused on the development, validity and reliability of the functional scales (both JIA-specific and generic).

These six instruments differ significantly from one another, and have been developed with different objectives in mind, giving each its own unique qualities.
The CAHP is a promising instrument. Despite its complexity, it can be filled out in the clinical setting in less than 15 minutes by parents and children. A user-friendly data-entry database has been developed to improve the ease of use in a standard clinical situation, and work is underway to simplify the scoring system.

CONCLUSION

The focus of this overview has been predominantly the six outcome measures that have been developed for JIA, and the attempt to measure functional status and/or HRQoL. These six instruments differ significantly from one another, and have been developed with different objectives in mind, giving each its own unique qualities.

The CHAIMS has been less well-studied and its measurement properties are not good; thus it is unlikely to have a continuing role.

The CHAQ and JAFAR have excellent measurement properties and have seen the greatest widespread use; they are simple to use and can be completed within a brief period of time. While the CHAQ and the JAFAR are of value as research tools, their greatest value is probably in the clinical setting. The CHAQ, by virtue of its applicability to all age groups, has a distinct advantage over the JAFAR.

The JAQQ also is comprehensive, although it can be completed more quickly than the JASI. The JAQQ can be administered to all age groups and is highly responsive; its most appropriate role is in clinical trials—the specific purpose for which it was designed.

The CAHP also has excellent measurement properties, particularly in its discriminative ability. It is comprehensive and cannot be completed quickly, so its role most likely will be as a research tool for longitudinal studies. It is important to note that both the JAQQ and the CAHP measure HRQoL and may thus be important for inclusion in long-term outcome studies in JIA.

With the expansion of the network of collaboration for clinical trials, it has been necessary to adapt instruments for use in several countries. To this end, PRINTO is encouraging both the adaptation and translation of both the CHAQ and CHQ to several languages, given the widespread participation in the trials that the organization is coordinating. As the work of PRINTO evolves, it will be interesting to see how these instruments perform in the broader international arena.

References

Rheumatoid arthritis (RA) is a disease characterized by joint destruction, leading to major disability, personal and societal economic burdens and reduced life expectancy. Evidence is accumulating that joint damage is an early phenomenon, and progresses relentlessly over the years. There is, moreover, a direct causal link between synovitis, anatomical damage and disability.1

A consensus has thus emerged over the years that the key goals of therapy in RA are early, rapid control of joint inflammation and prevention of joint destruction. To achieve these goals, disease-modifying antirheumatic drugs (DMARDs) are now being used in higher doses or in combination.

Recently, a better understanding of the pathogenesis of RA led to the development of a new class of DMARDs called “biologic agents.” These new drugs are capable of selectively targeting pathogenic elements of disease. Several of these agents, for example, have been developed to target tumour-necrosis factor alpha (TNFα), a pivotal cytokine in the disease process.

Based on the above premises and developments, an effective therapeutic regimen in clinical trials must demonstrate: clinical improvement (defined by the American College of Rheumatology [ACR] response criteria)2 and retardation of radiographic progression assessed by standardized x-ray scoring methods (the most widely used being the Sharp or the Modified Sharp techniques).3

Using data from well-designed, randomized controlled trials—and information gained from its wide pragmatic use—methotrexate (MTX) has emerged as the most widely used first-line DMARD. MTX is not only shown to improve the signs and symptoms of RA, but also to slow its radiographic progression.

Unfortunately, remission on MTX is achieved in few patients only, although a majority exhibit some clinical improvement (the so-called “partial responders”). The most significant unmet rheumatological need, therefore, is currently an effective agent to provide additional benefit to patients whose arthritis is only partially responsive to MTX.

**SINGLE DMARD THERAPY**

Two compounds will be considered worth reviewing here, of the few agents shown to have significant clinical efficacy and ability to retard disease progression:

**Leflunomide** (Arava™) is a novel immunosuppressive compound recently approved by the Health Protection Branch (HPB) of Health Canada for the treatment of RA. The principal mechanism of action of leflunomide is the inhibition of pyrimidine synthesis, thus reducing T lymphocyte proliferation and clonal expansion. Leflunomide was demonstrated to have comparable efficacy to MTX (average dose 13.5mg/week) in two separate trials, with an ACR 20 response around 40%.4 Interestingly, the ACR 50 and 70 responses were both superior to those found with MTX, demonstrating substantial clinical improvement in responders. Leflunomide also slowed disease progression in a fashion similar to that of MTX; moreover, when cases of MTX failure were treated with leflunomide in an open-label uncontrolled study, 50 % fulfilled the ACR 20 response criteria.

Controlled trials of leflunomide in combination with MTX are currently underway.

**Etanercept** (Enbrel™) is the soluble TNF-receptor fusion protein. This agent was the first to bring substantial improvement to patients with severe RA who failed to respond to several DMARDs, including MTX.5 In a head-to-head comparison to high-dose MTX in the treatment of early RA (less than three years duration), etanercept showed an earlier onset of action, with a trend to achieve a better ACR response rate.6 Both agents slowed structural damage in a conclusive fashion when compared to the predicted x-ray progression.
COMBINATION DMARD THERAPY
Two articles in the medical literature recently reviewed the different DMARD combinations.7,8 The excellent safety profile of MTX makes it the cornerstone of the five best combinations. In three of these combinations, the second DMARD was an add-on for patients with partial response to MTX.

**MTX plus cyclosporine A (CsA).**9,10 In a six-month placebo-controlled trial, the addition of CsA achieved a clinically significant response; in the extension phase, patients on placebo were switched to CsA and achieved the same rate of response after six months. Based on a previous placebo-controlled trial and an open-label cohort, CsA was shown to be capable of slowing radiographic progression.11,12 Thus although the MTX/CsA combination may be considered as a second step for partial responders to MTX, long-term toxicity (hypertension, increased serum creatinine) may limit its use.

**MTX plus etanercept.** The addition of etanercept (25 mg sc 2x/wk) achieved an ACR response rate never seen in previous RA clinical trials.13 In the open-label extension, in fact, with some patients reaching more than 30 months of therapy, this response rate was sustained. Coupled with a very benign toxicity profile, this combination seems to constitute one of the most efficacious therapeutic alternatives available.

**MTX plus infliximab** (Remicade™). Infliximab is a chimeric anti-TNF monoclonal antibody administered in combination with MTX by intravenous infusion every eight weeks. In the Anti-TNF Trial in Rheumatoid Arthritis with Concomitant Therapy (ATTRACT) trial, patients with long-standing, moderate-to-severe RA who had a partial clinical response to MTX were randomized to receive placebo or infliximab according to different dosing regimens.14 The four infliximab groups were statistically comparable to each other, and were superior to placebo; the retardation of radiographic progression in all four infliximab groups was even more impressive. Added to a good safety profile over one year, this combination appears to be one of the most efficacious therapies.

Two combinations were studied as first-line regimens in two separate clinical trials. The triple DMARD therapy—which, from the outset, combines MTX, hydroxychloroquine (HCQ) and sulfasalazine (SSZ)—was tested in a two-year study against HCQ + SSZ or MTX alone.15 The primary efficacy measure was a 50% improvement in the Paulus composite criteria by month nine of therapy, at which point nonresponders were dropped from the study. The triple DMARD group fared much better than the other two groups, with more than 75% of patients maintaining the 50% Paulus response by two years. The big limitations of this study are the very small number of patients (31 for the triple DMARD and 36 for the MTX alone) and the lack of any radiographic evaluation. A second trial, with similarly small groups of patients, was presented in an abstract format,16 but failed to duplicate the same extent of clinical response; only 46% of patients achieved the ACR 50 clinical response, compared to 36% for the MTX+HCQ group.

In the COBRA trial (Combinatietherapie Bij Reumaatoide Artritis) of early RA patients, the combination of SSZ (2 gm/day) + MTX (7.5 mg/week) + prednisone (60 mg/day and tapered over 28 weeks) was initially better than SSZ alone, but clinical efficacy was similar by week 58.17 The combination group, however, had a slower radiographic progression when evaluated at week 80. The lack of an “MTX alone” group (with increasing doses up to 17.5 mg to 20 mg) casts a serious shadow on the usefulness of such a combination.

In conclusion, there is ample evidence that if optimal benefit is not achieved with high-dose MTX (17.5 mg/week to 25 mg/week), the addition of TNF antagonists demonstrates a better benefit/risk profile and achieves the two-pronged goal of substantial clinical improvement and slowing of radiographic progression.
APPROPRIATE USES FOR ANTI-TNF THERAPY
The availability of existing treatments for RA demands that the use of new and more costly agents such as anti-TNF therapy be justified. Those therapies most commonly used (such as MTX) fail to prevent the high direct costs (e.g., frequent hospitalization, joint-replacement surgery) and indirect costs (e.g., disability, premature death) of this disease.

There is enough evidence to draw a consensus that it is appropriate to add anti-TNF therapy to an existing regimen of MTX and/or other DMARDs that have failed to achieve sufficient beneficial effect. One would not add anti-TNF therapy without first establishing lack of disease control through treatment with a DMARD—usually MTX at a minimum dosage of 15 mg/week for at least three months.

References

Anti-TNF therapy also could be considered as a first DMARD for patients whose comorbid conditions might contraindicate other agents, such as those with severe liver or renal diseases.

RECOMMENDATION
Given the high disability rate and shortened life expectancy of patients with RA, it is the strong consensus of the Canadian Rheumatology Association that effective therapy with TNF antagonists be made available as soon as possible, and be made readily accessible—through provincial drug plans and private insurers—to all patients for whom this therapy is deemed appropriate. It is expected that the early high cost of TNF antagonists will be offset by lowering the higher costs of morbidity, decreased productivity and earlier mortality.
An Interview with Dr. Jean-Pierre Pelletier

Dr. Jean-Pierre Pelletier was honored with the CRA Distinguished Scientist Award this past season for his contribution to the field of rheumatology research in Canada. Through his experiences, we reflect on this specialty.

Q Dr. Pelletier, what encouraged you to choose rheumatology as a career?

During my medical-school training at the Centre Hospitalier de l’Université de Montréal (CHUM) in the late ’70s, I did a rotation in rheumatology. It impressed me that there was still so much to be done to alleviate the suffering of patients with arthritis.

My bachelor’s degree from the Université de Montréal was in biochemistry, and I found that research into osteoarthritis was still, at that time, a fairly virgin field. It was also being postulated that arthritis was more of a biochemical disease and, because of my background, this piqued my interest.

An opportunity for training arose with Dr. David Howell in Miami, Florida, supported by the Arthritis Society. Dr. Howell was pioneering research into the pathophysiological pathways of OA, and the role of proteolytic enzymes. He was discovering that the target for OA treatment was the inhibition of proteases. This provided a wonderful opportunity for me as a trainee and, as a MD scientist, was particularly compelling.

Such a start afforded me involvement in the scientific community, which later allowed me to contribute to the global understanding of the pathophysiology of OA.

Q How has rheumatology in Canada changed over the course of your career?

The field has changed in this country but, I’m afraid, not for the better.

Over the last 10 years, Canada has seen a decrease in both academic rheumatologists and scientists. The development of academic rheumatologists, which has traditionally been driven by university support, seems to have dried up. I personally feel that it will be difficult for academic rheumatology in this country to survive the current trend. At our Center (the Arthritis Center of CHUM), we train on average only one new rheumatologist per year. How will this replace the number of rheumatologists who will be retiring in the next 10 years? If we can’t be more proactive in bringing training candidates into the field, patients may not have access to a rheumatologist when they need one.

This lack of academic support is further affecting our ability to draw MD scientists to the field. The comprehensive knowledge and direction an MD scientist brings to a research team are indispensable.

Dr. Jean-Pierre Pelletier, MD
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MISSION STATEMENT
The mission of the CRA is to represent Canadian rheumatologists and promote their pursuit of excellence in arthritis care and research in Canada through leadership, education and communication.

UPCOMING RHEUMATOLOGY MEETINGS
Mark your calendar! The next Annual Winter Meeting of the CRA will be held in Mont Tremblant, Quebec from Feb 21-24, 2001. Dr. Paul Haraoui (paulharaoui@ibm.net) of Montreal is the Program Chair. Also, note that ILAR (Intl League of Associations for Rheumatism) will be held in Edmonton Aug 21-25, 2001, with Tony Russell as President of the Meeting and Paul Davis as Program Chair.

NEEDS ASSESSMENT IN 2000
In 1993, the CRA, with Paul Davis as President, undertook the first comprehensive needs assessment of the CRA membership, which led to the CRA of today. This year, a follow-up needs assessment will be developed by Glen Thomson and Denis Choquette with the assistance of Paul Davis. This new assessment is being undertaken to ensure that the CRA continues to meet the needs of its members. Please be sure to complete the survey when it arrives in the mail!

INDUSTRY COUNCIL ESTABLISHED
The CRA has established an Industry Council, with the assistance of Jean-Claude Dairon, who will act as a consultant in strengthening the CRA’s relationship with industry, especially at the time of the Annual Meeting but also throughout the year. The Executive anticipates new initiatives and opportunities to be presented to the membership during the upcoming year. If you have any suggestions please contact the Secretary.

COMMITTEES
Do not hesitate to contact your committee chairpersons (below) with concerns, suggestions or assistance. The CRA website continues to evolve and mature; for access to the site, contact Steve Edworthy or the Secretary.

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Research opportunities like the one I benefited from following my medical training are gone. In the last 10 years, only one of our trainees has decided to go into research. This is definitely affecting the impact of Canadian rheumatology on the global scientific community.

How do you see the future of rheumatology evolving in Canada?

We will have to take the bull by the horns and look critically at where this field will be in 10 years. This is not a financially glamorous field, and fees for clinical rheumatologists have not increased in the last five years in many provinces. As a result, we have lost a handful of rheumatologists to other professions over the income issue alone, at a time when more manpower is tremendously necessary. And, as I noted, we’re not getting the new rheumatology candidates we need. The lack of funding for research is also going to have to be addressed.

What advice would you give to those following in your footsteps?

I would suggest to new rheumatology scientists that they be cautious, and to make sure they enter this field working with a group where there is opportunity and potential to become an independent investigator.