

# Management of Patients With Rheumatoid Arthritis in Latin America

## *A Consensus Position Paper From Pan-American League of Associations of Rheumatology and Grupo Latino Americano De Estudio de Artritis Reumatoide*

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**Objective:** A consensus meeting of representatives of 18 Latin-American and Caribbean countries gathered in Reñaca, Chile, for 2 days to identify problems and provide recommendations for the care of patients with rheumatoid arthritis (RA) in Latin America, a region where poverty and other health priorities make the efforts to provide effective and high quality care difficult. This report includes recommendations for health professionals, patients, and health authorities in Latin America, with an emphasis on education and therapeutic issues.

**Methods:** Fifty-one rheumatologists (list available only online on the JCR website) from 18 Latin-American and Caribbean countries with a special interest in RA participated in the consensus meeting. Participants were experts identified and appointed by the National Societies of Rheumatology affiliated with the Pan-American League of Associations for Rheumatology (PANLAR) and by the Grupo Latino Americano De Estudio de Artritis Reumatoide (GLADAR)—an independent group of Latin American rheumatologist researchers were also invited to the meeting. Eight topics were

identified as priorities: patient, community and allied health professional education, health policy and decision making, programs for early detection and appropriate treatment of RA, role of classic disease modifying antirheumatic drugs (DMARDs), role of biologic therapy, and drug safety surveillance. To reach consensus, a survey with questions relevant to the topic of interest was sent to all participants before the meeting. During a 2 day meeting, the answers of the survey were reviewed and discussed by each group, with final recommendations on action items.

**Results:** The specific topic of the survey was answered by 86% of the participants and 68% of them answered the entire survey. It was agreed that RA and rheumatic diseases which are currently not but should be public health priorities in Latin America, because of their prevalence and impact on quality of life.

**Conclusions:** Strategic areas identified as priorities for our region included: early diagnosis and access to care by multidisciplinary teams, creation of databases to identify infections with the use of biologic agents in RA which are relevant to Latin America, and overall efforts to improve the care of RA patients in accordance with international standards. Implementation of educational programs aimed to improve self-management for patients with RA was also considered crucial.

**Key Words:** rheumatoid arthritis, Latin America, diagnosis, treatment  
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A report from PANLAR AND GLADAR Consensus Meeting on Education and the Use of DMARDs and Biologics in Latin American Countries; October 3–4, 2005; Reñaca, Chile.

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Latin-American and Caribbean countries share key social problems: poverty, violence, unemployment, lack of education, and marked inequity that have a negative impact on health.<sup>1</sup> In this region there are wide variations regarding health priorities. Public health efforts are primarily focused on controlling infectious transmissible diseases and mother and child care. Health policy related to chronic disabling diseases takes a second place in relation to these areas.<sup>2</sup> Strategic public policies traditionally consider conditions that impact mortality and life expectancy, while overlooking chronic conditions such as RA, which in addition to have major impact on quality of life and morbidity, is now recognized for its impact on mortality. This is challenging for Latin American rheumatologists because it is a treatable cause of disability in the Western world,<sup>2</sup> but it requires investment in health policies that can ensure early diagnosis, coordination of multidisciplinary care and education efforts, extensive availability of well-established pharmaceutical resources, and equitable distribution of effective but expensive new therapies.

RA affects approximately 0.4% of the Latin American population over 16 years of age<sup>3–5</sup> and is much more common in women than in men: 6 to 8 to 1.<sup>6</sup> The course of RA is variable, but for a

significant number of patients RA is a severe disease resulting in chronic pain, progressive joint destruction, functional decline, and premature death.<sup>7-9</sup> Equally important is the loss of social and financial independence, very relevant in developing countries, which have a high prevalence of poverty.<sup>10</sup> The disease exerts a considerable burden on society in terms of medical care and the effects on patients' ability to work,<sup>11-14</sup> especially those in manual labor occupations.<sup>11,15</sup> Women and those people with adverse socioeconomic status have the worse prognosis.<sup>16</sup> The increasing recognition that RA is not a benign disease has changed the therapeutic approach to more aggressive and timely interventions.<sup>17</sup> Erosive changes leading to joint destruction often occur early in the disease, and the resulting functional disability may be irreversible.<sup>18-23</sup> Early diagnosis and treatment before the onset of damage offer "a window of opportunity for intervention,"<sup>24,25</sup> shown to improve long-term outcomes.<sup>26</sup> There is an agreement that RA should be treated as early as possible with disease-modifying antirheumatic drugs (DMARDs) to control symptoms and probably delay disease progression.<sup>27-31</sup> Evidence-based guidelines for the management of RA are available in Europe, Canada, United State of America, and Latin America<sup>3,32-36</sup> emphasizing early access to rheumatologists, early use of DMARDs, precise indications of biologic therapies, rehabilitation, and patient education. A multidisciplinary team approach with participation of rheumatologists, general medical practitioners, nurses, occupational therapists, physical therapists, podiatrists, nutritionists, and psychologists has been recognized as the foundation for comprehensive and holistic care of patients with RA.

There is a substantial unmet medical need in the treatment of RA for patients from Latin American and Caribbean countries. Many patients with RA see a rheumatologist too late in the course of their disease, do not receive DMARDs early on, and have no access to musculoskeletal rehabilitation services or relevant educational programs.<sup>3</sup> Drug therapy alone does not substantially improve quality of life or the ability to go back to work in RA patients, and patient and community education are necessary to empower patients and their families in their daily management and adjustment to their chronic illness.<sup>37-39</sup> Education is an issue of particular relevance to our region where alternative and folklore medicines are in great demand. Moreover, there is a public perception that there is no effective allopathic therapy for RA.

Rheumatologists from 18 Latin American and Caribbean countries representing the National Societies of Rheumatology affiliated with the Pan-American League of Associations for Rheumatology (PANLAR) and the Grupo Latino Americano De Estudio de Artritis Reumatoide (GLADAR) as well as experts from United States and Canada met in Reñaca, Chile in late 2005 to reach consensus on the major problems threatening the care of RA patients in the region and to provide recommendations for physicians and policy makers on the development of local agendas to enhance daily practice and quality of care.

## MATERIALS AND METHODS

Participants in the consensus were 51 rheumatologists from 18 Latin-American and Caribbean countries (Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, Ecuador, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Uruguay, and Venezuela) with a special interest in RA identified through the Executive committee of PANLAR, its affiliated National Societies and GLADAR. This list is available on the website. In addition, an expert from Canada and 3 from the United States participated in the meeting. Eight topics were identified as priorities for discussions and recommendations: (1) patient education; (2) community education; (3) allied rheumatic disease health profes-

sionals education; (4) health policy and decision making; (5) programs for early detection and appropriate treatment of RA; (6) role of classic DMARDs; (7) role of biologic therapies; and (8) drug safety surveillance. Four coordinators were each appointed to lead the discussions for 2 of the groups. Participants from different countries were divided into 8 topic groups.

All participants were contacted by e-mail. As preparatory work, the coordinators identified key literature related to the issues of interest which was distributed among groups. In addition, each coordinator prepared a short assessment survey that was sent to all of them before the consensus to obtain information related to the identified topics from all participating countries. Most of the questions were related to the specific needs, available resources, and priorities for each country.

At Second round, 86% of participants answered their corresponding questionnaires. To reach consensus conclusions a third round modified Delphi study was conducted.<sup>40-42</sup>

During the first day of the consensus meeting, invited experts provided background and topic relevant information for the discussions. These included Dr. Kate Lorig who discussed self-care programs in chronic diseases and arthritis, Professor Aristides Torche, an economist with expertise on the effects of poverty on health, and Dr. Fernando Muñoz, a member of the Chilean Health Ministry, who described decision-making processes in health policy. Consensus discussions were led by the coordinators of each topic group. At each session, the preliminary survey results were presented and critically analyzed. Recommendations were drafted for presentation to all participants at large. All discussions were framed within the context of Latin America's health, economic, and socio-cultural current situation, and available resources.

On the second day, the recommendations of the group discussions were presented and discussed at a plenary session including all participants. Final consensus was reached with respect to recommendations and future action plans.

## RESULTS

The following sections summarize the results of the survey, consensus recommendations, and action plan for each of the priority areas. While many of the recommendations are related exclusively to RA, many others, in particular those related to community and policy efforts, encompass rheumatic diseases at large.

### Patient Education

#### Survey

The survey indicated that there are local educational efforts directed to rheumatic patients in each country, but that they vary in format, content, and target audience, some directed to patients and others to the community. None of the programs have been formally evaluated. Participants agreed that RA patients in their respective countries had poor knowledge about their disease: 71% of participants identified the overall level of knowledge of educated patients (high-school or higher) as mediocre, low or very low; 98% agreed that patients with an incomplete high-school education had little or very little knowledge about their disease.

#### Proposed Action Plan

1. To develop high quality educational programs for RA patients including knowledge about their disease manifestations and all available therapies and self-care management. It was proposed that local adaptations of the self-care program "Spanish Chronic Disease Self-Management" developed by Dr. Kate Lorig should be encouraged. Efforts should be locally channeled through patient organizations and Rheumatology National Societies.

- To provide training for health educators to implement education programs at local and regional settings. PANLAR was identified as a key stakeholder to find resources to provide training for health educators in various countries, by targeting governments and soliciting unrestricted educational grants from industry.

## Community Education

### Survey

Most participants agreed that RA is not a health priority for their governments (69%), that there are no governmental programs for rheumatic diseases (94%), that the Bone and Joint Decade declared by the World Health Organization (WHO) has had no impact in the recognition of RA as a major problem (65%), that the population of Latin America is uninformed about RA (81%), and that many patients look for help of traditional or alternative medicine (56%). There was an agreement that the existing community programs are variable, that many programs sponsored by industry have poor quality, that there are no awareness and specialized information programs for the general public, and that there is insufficient coverage about arthritis in the media.

### Proposed Action Plan

To develop local public education and dissemination educational programs targeting communities, led by rheumatologists with active participation by allied health professionals and patients. The overall aim of these programs is to increase awareness of the impact of RA on the population at large and the importance of early diagnosis and treatment.

## Allied Health Care Professional's Education (Nurses, Rehabilitation, Occupational Therapists, and Physical Therapists)

### Survey

More than 90% of the participant countries have training and educational programs for allied health professionals, as well as master and PhD degrees in these disciplines, as well as medical specialization for physicians. In about 50% of the countries there are public resources destined to the education of allied health professionals, but in general terms, these are not intended for training in rheumatic diseases or musculoskeletal diseases. Eighty-six percent of the participants stated that these disciplines were not represented in dissemination efforts related to arthritis care; 83% of them estimated that these services are quantitatively inadequate in their countries.

### Proposed Action Plan

- To stimulate the publication of scientific information related to educational programs in occupational therapists, rehabilitation, and physical therapists directed at rheumatic diseases, particularly RA.
- To promote scientific sessions, workshops, symposiums, or lectures on topics related to occupational therapists, rehabilitation, and physical therapists in all scientific activities supported by PANLAR.
- To support the implementation of governmental policies specific for rheumatic diseases in these areas, endorsed by the National Rheumatology Societies, including financial support for training programs for health professionals caring for rheumatic patients.
- To create a PANLAR study group in this discipline, which can develop educational, training, and therapeutic guidelines to be used by allied health professionals caring for rheumatic patients.
- To foster an integrated multidisciplinary approach involving various care providers working with rheumatologists in the management of rheumatic diseases.

## Health Policy and Decision Making in RA

### Survey

There was an agreement among all participants that there is little information and published data on the epidemiology, burden of illness, and economic impact of RA in the region to inform health authorities about key issues. Participants also agreed that our countries lack policies regarding incentives for specialty rheumatological care that ensure patient access to rheumatologists. There were country-specific discrepancies regarding patient access to drug therapy. While most countries do not have policies on this regard, some countries do. Most participants agreed that scientific societies such as the National Rheumatology Societies had little influence on governmental policy, but in some countries the societies had been influential in decision making. There was an agreement that there is no public or governmental support in the region for research in rheumatic diseases. Despite the fact that almost all countries have National Research Institutes granting funds, very few of them are directed to rheumatic disease research.

### Proposed Action Plan

- To disseminate existing local and relevant data to health authorities. There is a pressing need for epidemiologic and health services information on RA in Latin America. PANLAR and the Rheumatology Societies should make the existing data available to health authorities.
- To conduct research in the following priority areas: burden of rheumatic diseases, impact on patients, families and the whole society, direct and indirect costs of RA. In this regard it was agreed that the first position paper on RA in Latin American countries in progress at the event<sup>3</sup> would be a very important tool to inform authorities. It was recognized that GLADAR's early RA cohort study, which started in 2004 is a useful initiative as it provides information on clinical features and patient's needs in Latin America.
- To identify other local, national, and international organizations and stakeholders with key roles in policy making. International organizations such as the WHO, Pan American Health Office, the United Nations, and the World Bank should also be targeted.

## Programs for Early Detection and Appropriate Treatment of RA

### Survey

Early RA was defined as 12 months from first symptoms by 45% of participants. Most participants (89%) agreed that an early definite diagnosis presents difficulties, but 98% agreed upon the concept of a therapeutic window of opportunity early in the course of the disease. Sixty-five percent felt that anti-CCP antibodies could be considered a validated diagnostic tool and predictor of radiologic progression of RA (70%), even though only 57% reported having access to this test in daily practice. Imaging with ultrasound (US) (86%) and magnetic resonance imaging (MRI) (93%) were acknowledged as highly sensitive methods for recognizing synovitis and erosions. However, 73% considered radiographs as a better tool to follow therapeutic response because US and MRI are expensive and not widely available, and diagnosis and follow-up should rest upon the least expensive and most widely employed methods for the time being. Although health assessment questionnaires (HAQ), visual analogue scales (VAS), and disease activity scale with 28 joints assessed (DAS28) are known to give valuable information, they were not routinely used in the experience of the participants, because performing these tasks will be time consuming in a busy clinic.

## Proposed Actions

To increase the early suspicion and diagnoses of RA and to make a rapid referral to rheumatologists the following actions were proposed:

1. Adequate training of general practitioners, general internists, and allied health professionals in articular examination and RA symptoms. This could be done with assistance from PANLAR through National Societies of Rheumatology.
2. Creation of early arthritis clinics or areas within rheumatology units to provide care for patients referred early in the course of their disease. Where available, US could be used in cases of early synovitis and clinical doubt.
3. Training of rheumatologists in US techniques as this technique is increasingly being used in outpatient settings and is of particular value in early diagnosis.
4. Training in interpretation of MRI where available.

## The Role of Classic DMARDs

### Survey

The survey asked which physicians prescribed DMARDs in their countries, 62% answered that internists also prescribed DMARDs; other responses included generalists 19%, orthopedic surgeons 5%, others 13%. Fifty percent of the participants stated that in their countries sequential mono-therapy was preferred, whereas the other half stated that they preferred combination therapy. Most participants (88%) said that in their countries the most common strategy was step-up therapy, compared with 12% for step-down therapy. The preferred DMARD combination was methotrexate and chloroquine or hydroxychloroquine; next DMARDs used after failure were sulfasalazine or leflunomide. The most widely available DMARDs were methotrexate, leflunomide, and azathioprine. Methotrexate and corticosteroids were commonly included as medications under covered insurance, but often patients had to pay for other DMARDs out of their own pockets. Most participants (80%) agreed that the monitoring interval for patients using DMARDs varied between 1 to 3 months, 18% stated it varied between 3 to 6 months, and 2% stated it varied more than 6 months. Eighty-five percent have used tools like HAQ or DAS28 to monitor disease activity but this is not a daily practice. Also 68% of participants ask for laboratory tests to monitor possible adverse effects of DMARDs. There was an agreement (95%) in the use of biologics after DMARDs failure, but there was no agreement on what should be the length of time before considering a therapy to have failed. Biologics were used in combination with a DMARD by 97%. Sixty-seven percent of participants agreed that biologic agents have modified the treatment strategy in RA.

## The Role of Biologic Agents

### Survey

There was an agreement that biologic agents are available in all countries except Cuba, where only rituximab is available. All participants agreed that they should be prescribed only by rheumatologists, and that there are no criteria on duration of therapy and doses once they have reached their therapeutic objective. At the moment, all biologic drugs appear to be equally effective, but there have not been drug study trials comparing their efficacy head to head. The participants agreed that a combination of biologic agents should not be used. It was agreed that biologics are expensive and that a small proportion of RA patients from this region have access to them through private or national health plans. However some patients have the limited access to these therapies offered by clinical drug trials.

## Proposed Actions

1. It was estimated that 25% of RA patients would not respond to DMARDs.<sup>32</sup> These patients should be treated with biologic agents combined with DMARDs and during some periods with corticosteroids or anti-inflammatory drugs.

Criteria for Using Biologic Agents in Latin-American RA Patients.

- i. Patients having the diagnosis of RA according to American College of Rheumatology criteria.<sup>43</sup>
  - ii. Active disease measured by a disease activity scale such as DAS28  $\geq 3.2$ <sup>44</sup> and after at least 3 months on conventional treatment with DMARDs.
  - iii. Patients should have used 2 DMARDs, 1 being methotrexate in adequate doses, unless there were significant adverse effects.
  - iv. Adequate doses of methotrexate should have been up to 25 mg weekly via oral, intramuscular, or subcutaneously, and leflunomide 20 mg per day; with the exception of patients presenting adverse events limiting the use of these therapies.
  - v. Patients should be in functional American College of Rheumatology status<sup>45</sup> I, II, or III.
2. Special cases considered to have indications for biologic agents included those patients with a clinically adequate response to DMARDs but with progressive erosive disease; patients with persistent arthritis in major joints for function and activities of daily life such as: hands, knees, and hips. Also, those with contraindications to the use of DMARDs.
  3. Assessment of response to treatment should be measured quantitatively with tools such as: DAS28, HAQ, patient global assessment by visual analogue scale.
  4. There was an agreement that a history of latent tuberculosis (TB) should be elicited and that even though BCG vaccines are compulsory in Latin American countries, PPD testing should be used. Prophylaxis with isoniazid ought to be started before using biologic agents if any of the following items are positive: PPD  $\geq 5$  mm, chest radiograph with images of old TB or suspicious contact.

## Drug Safety Surveillance

### Survey

Seventy-five percent of participants reported that there were no pharmacovigilance programs for patients with rheumatic diseases in their countries, but most of them (93%) agreed on the importance of having such programs, especially for RA, given the high prevalence and incidence of infectious diseases in Latin American and Caribbean countries. Sixty-one percent of the participants agreed that this should also contain information on efficacy of drugs, although they were aware that obtaining these data would probably be increasing costs and adding to the difficulties of implementing the program.

## Proposed Actions

Most participants agreed that a pharmacovigilance program should be established by the governmental health agencies, accessible via internet. Most physicians present at the meeting would be willing to report TB or other infectious diseases in patients with biologics to a central data base if there was such an initiative. To implement and develop existing programs, the group agreed that the Rheumatology Societies represented by PANLAR should coordinate a collaborative effort with local governmental agencies, multinational institutions like the WHO and the Bone and Joint Decade in collaboration with the pharmaceutical industries to sponsor and implement such programs. The proposal was to create a pharmaco-

vigilance report system managed by PANLAR. With this tool, rheumatologists could report all cases that required hospital admission, life threatening events, or treatment withdrawal.

## DISCUSSION

RA is a potentially treatable disabling disease affecting mostly women in their prime years. New discoveries in the RA field should give hope for better holistic therapeutic strategies to all Latin-American and Caribbean patients with RA, even considering the high costs of biologic agents that prevent their use where indicated. During the meeting, plans to proceed considering the Latin-American and Caribbean reality were established. Implementation of educational programs aimed to improve self-management for patients with RA are considered crucial. Other strategic areas identified as priorities for our region included: to facilitate the early diagnosis and access to therapy, care by multidisciplinary teams, creation of databases to identify infections with the use of biologic agents in RA, which are relevant to Latin America, and overall efforts to improve the care of RA patients in this region, in accordance with international standards. Funding research to obtain regional data in many aspects of the disease was thought relevant to include RA in public health priorities. As there is a need to provide better information for those who are providing care and those who are paying for it, Rheumatology Societies should encourage research projects on the economic and social burden of rheumatic diseases within each country. In addition, other relevant issues remain to be addressed such as accelerated atherosclerosis.<sup>46,47</sup>

The PANLAR-RA Study group, the PANLAR-Standing Committee of Epidemiology could fulfill a critical role collaborating with other initiatives, such as international entities, to answer questions raised from cost-effectiveness studies of new treatments in RA using the appropriate instruments for measuring patient-centered outcomes. The local media's role in research broadcasting or diffusion of epidemiological data, disease impact, and on influencing policy makers and the public itself was emphasized.

Almost 3 years have passed since the October 2005 meeting and some efforts can be highlighted. The following section summarizes a progress report for each topic.

### Patient, Community, and Allied Health Professional Education

The patient education program "Cómo convivir con su artritis" licensed by Stanford University has already started in Ecuador, Chile, and Mexico. In 2006, a group of 14 health professionals from Argentina, Brazil, Chile, Colombia, Ecuador, Peru, and Venezuela was formed as trainers in a week course held in Panama City organized by GLADAR. Forty Chilean RA patients have been reached with the program and 12 new monitors are able to replicate the workshops. No progress is made on community education. PANLAR has established a new standing committee: The Health Associated Professionals. PANLAR has launched its "PANLAR Bulletin on Line" where articles about RA and other rheumatic diseases published in the American National Journals (not all of them available through PubMed) will be available out of country boundaries.

### Health Policy and Decision Making

Today, economic surveys related to RA are being developed in Argentina, Chile, and Mexico. The early onset RA GLADAR's cohort continues. Since the end of the meeting, little has changed in Latin American countries regarding information and published data on the epidemiology, burden of illness, and economic impact of RA. There has been, however, in an attempt to regulate the use of expensive new drugs, more involvement of local Rheumatology Societies in the generation of guidelines. In that regard, for example,

the Brazilian,<sup>33</sup> Argentinean,<sup>36</sup> and Chilean<sup>48</sup> guidelines for the treatment of RA have recently been released. In Mexico, the Colegio Mexicano de Reumatología is attempting to include RA into the health governmental priorities and the cost of RA treatment for the poor is paid by a special insurance agency.

### Programs for Early Detection and Appropriate Treatment of RA, Role of Classic DMARDs, Role of Biologic Therapy

Anti-CCP antibodies and US has become more available. Although still not widely accessible, the concept of the need to incorporate US in rheumatology training is becoming well recognized. Early clinics offering free quick access to rheumatology care with an emphasis on early referrals are functioning in Brazil, Peru, and 2 in Mexico City, although their impact on breaking the breach between early disease and specialty care has not yet been evaluated. Some more insurance companies and governmental support is allowing biologics for patients not responding to conventional DMARDs, but the proportion of patients getting these therapies is still limited.

### Drug Safety Surveillance

The Brazilian governmental health agency has instituted a pharmacovigilance website<sup>49</sup> with a program for reporting drug adverse reactions (not exclusively for Biologics) and official actions. The PANLAR General Assembly of Boston (November 2007) approved the implementation of a Registry of Adverse Events of Biologic Agents used to treat RA and other inflammatory arthritis following the model of BIOBADASER, the register of the Sociedad Española de Reumatología.<sup>50</sup> As a result, the majority of the National Societies of PANLAR have subscribed commitment for its implementation at a country level. The Mexican College of Rheumatology has already started the recruitment of more than 100 patients. In several other Latin American countries similar initiatives have been or are currently being implemented. The lack of appropriate funding for these programs could be a serious threat to their development.

Institutions from all participant countries endorsed the Bone and Joint Decade, which intends to fight for the disability impact of untreated RA. In Latin America and the Caribbean region with an estimated total population of 562 million inhabitants, 2000 rheumatologists are registered in PANLAR. We need 6244 and we have a 32% provision (the optimal provision of rheumatologists would be 1 full time equivalent consultant rheumatologist per 90,000 population).<sup>51</sup> Owing to few qualified rheumatologists in proportion to the population of the region, recommendations are difficult to become reality, however, a change in health policies would bring support to rheumatologists working in Latin America and Caribbean countries to give better health.

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