

Title: A consensus position paper from REAL-PANLAR group about the methodological approach for the accreditation process of Centers of Excellence in Rheumatoid Arthritis in Latin America.

Short Title: A guide for the process of accreditation of centers of excellence in rheumatoid arthritis.

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ABSTRACT

Background: By 2015, the World Health Organization (WHO) reported that 1% of the world population suffered from Rheumatoid Arthritis (RA) and in Latin America (LATAM) between 0.5% and 1%. Previously, in May 2014 a consensus meeting was held in Barranquilla, Colombia, where the Project for Implementation and Accreditation of Centers of Excellence in RA in LATAM was established, which then became an official special group of PANLAR.

Objective: To define the methodological approach for the accreditation process of centers of excellence in RA in LATAM.

Methods: A meeting was held in April 2015 with participation of the members of the REAL-PANLAR Steering Committee (SC), and representatives of several LATAM countries, with the support of two experts in accreditation processes and models in Colombia. One of the members of the Steering Committee introduces participants to a preliminary proposal for the accreditation process of centers of excellence in RA in LATAM. It defined by common agreement the affirmative participation of 100% of participants in a single round. The results of the consensus were transcribed by a trained assistant who attended the entire meeting. Then in November 2015, in San Francisco and in November 2016, in Washington, the REAL-PANLAR SC meets to discuss some final aspects of the project.

Results: The following steps for accreditation were defined: Application for accreditation, issuance of the concept of assessment of the entity, accreditation decision and monitoring accreditation.

Conclusions: This is the second REAL-PANLAR consensus whose purpose was to define the parameters for the accreditation process for future centers of excellence in RA in LATAM.

Key Words (MeSH): Rheumatoid Arthritis, Latin America, Quality of Health Care , Accreditation, Standard of Care

INTRODUCTION

By 2015, the World Health Organization (WHO) reported that 1% of the world population was suffering from Rheumatoid Arthritis (RA), in Latin America (LATAM) between 0.5% and 1% (1). This problem has meant that the different actors involved in the administration of this condition take responsibility together to address the management of the disease. This purpose involves not only a good medical practice, but should deal with administrative and logistical aspects that would make health care comprehensive (2).

In LATAM and the Caribbean, health systems differ in their organization, generating variation in the protocols for the same pathology without ensuring a comprehensive treatment (1, 3). For this reason, emerging strategies such as the Centers of Excellence (CoE), which aim to unify and improve care by implementing homogenous standards, consolidating multidisciplinary care, generating new knowledge and continuously improving logistics and administrative processes, thus ensuring patient access to specialized care (2). Moreover, the lack of quality care directly impacts the provision of care services, which are directly related to obtaining favorable results. Despite scientific advances in health, the effects of healthcare processes show a significant gap between what actually happens and what the health system should offer (2-4). Beyond the causal analysis, recognizing the difficulties in ensuring quality health care from the first levels made it possible to focus the need to redesign systems and care processes to generate value, i.e. towards achieving the best results in relation to cost (5-8).

The definition of quality and methodologies to ensure quality health care, focus on the scope of clinical performance objectives in terms of effectiveness and safety (9), these being fundamental concepts for the development of CoE. In this way, organizations can create value, meaning that quality is the differentiating factor, which is directly related to the results in the patient. In addition, the generation of a network of CoE in RA is a strategy that would improve quality, through the development of programs and comprehensive care models (5, 8, 10). Consequently, organizations, programs, or health institutions that want to demonstrate excellence should concentrate clinical activities on early diagnosis, controlling inflammatory activity, in reducing radiographic progression, in the improvement of functional capacity, and generally preserving the quality of life (5, 11, 12). Thus, accreditation emerges as a methodological process of support to institutions that wish to improve their standards of care in this condition. (13, 14).

The focus of accreditation programs in health is based on structure (SS), process (PS) and result (RS) standards, which are articulated to each other and are a consequence of each other. Additionally, if the comparison pattern is

standardized, the improvement and results of accredited programs in the care of patients with RA generates a greater impact on disease management (8).

REAL-PANLAR met in May 2014, and in order to address this problem, invited experts in rheumatology and health management for a consensus of experts who built the requirements for creating the CoEs in RA, where a conformity classification was generated according to their complexity considering structure, processes and results (1, 3):

✓ Standard CoE

✓ Optimum CoE

✓ Model CoE

Once this new problem was defined and taking into account the results of the 2015 consensus the following questions emerged:

- **Who must accredit the CoE's operation?**
- **What should be the process or procedure to accredit a CoE?**

To answer these concerns this article aims to present a consensus of experts to determine the logistics and methodological approach for the accreditation process of Centers of Excellence in Rheumatoid Arthritis.

METHODS

This initiative is currently endorsed by PANLAR and according to a memorandum of understanding REAL-PANLAR is becoming a Special Group of PANLAR; at the same time REAL-PANLAR has a steering committee (SC) who rules all activities inside the group; as a special group and according to the memorandum of understanding, REAL-PANLAR intends to implement the model of CoE for Latin America and for this reason emerges this methodological approach for the accreditation process of CoEs in RA. REAL-PANLAR meets again in April 2015 in the city of Barranquilla, Colombia in the framework of the PANLAR Review Course. The members of the SC of REAL-PANLAR and an expert group in RA, who also participated in REAL-PANLAR 2014, were summoned. The developer group was formed as follows:

- A coordinator (Colombian rheumatologist), member of the SC of REAL-PANLAR, who structured the theoretical and methodological contents result of the first meeting (1).

- A representative of the scientific societies of rheumatology of the following countries: Argentina, Brazil, Chile, Costa Rica, Dominican Republic, Ecuador, El Salvador, Mexico, Paraguay, and Uruguay.
- An expert in disease management and accreditation in health who advised the group on issues related to quality accreditation for the provision of health services.
- An auxiliary in charge of consensus organization.

Consensus was defined as an affirmative or negative response of all participants (100%) in a single round of nominal character. The discussion was recorded and transcribed by the assistant in charge, who attended the entire meeting. At the end of the consensus, the experts provided the reviewed literature for inclusion in this manuscript, taking into account as principal document the article titled “REAL-PANLAR Project for the Implementation and Accreditation of Centers of Excellence in Rheumatoid Arthritis Throughout Latin America” published in June, 2015, which established quality standards and center of excellence categories. This first meeting was attended by rheumatologists with expertise in disease management and AR patients (1).

Afterwards the first proposal for methodological approach for the accreditation process of Centers of Excellence was created and presented in November 2015, the SC of REAL-PANLAR met in the city of San Francisco, USA in order to socialize and review the preliminary results of the consensus and to adjust a new version.

Finally in November 2016, the SC meets in Washington, USA to discuss some final aspects of the project, to review and adjust the final version.

RESULTS

Constitution of the accrediting body

- ✓ An accrediting board denominated REAL-PANLAR Center of Accreditation for Rheumatoid Arthritis (CARPAR, for its initials in Spanish) will be created, constituted by four experts in rheumatology who will represent the North Zone, Central America and the Caribbean, the Andean region and the Southern Cone, and one expert in quality assessment (Figure 1).

Additionally, it will include two evaluators virtually and/or in person, who will assess the centers to finally deliver a report to CARPAR, who will evaluate and issue the final concept.

- The evaluation form is the result of the 2015 expert consensus, where the criteria for the classification of CoE were defined. These parameters could be subject to permanent review by the SC who will turn them into indicators, subjectable to measurement (Table 1).
 - CARPAR members will be appointed by the REAL PANLAR SC, and have tenure of two years.
- ✓ CARPAR will be independent from PANLAR, and will be responsible for dealing with special controversies regarding the processes in its charge; however, REAL-PANLAR will be responsible for generating the accreditation of the CoE.
- In order to maintain the philosophy of transparency during the process, accreditation visits will be conducted by the evaluating group (formed by experts in accreditation in health auditing who may not be rheumatologists or other related professionals who have direct relationship with any of national associations or rheumatology centers that can be accredited) rheumatology.
 - CARPAR's decision to do the verification visit will be subject to compliance with the mandatory minimum criteria (MMC) for CoE, which fall under the criteria of *structure* which are detailed in Table 1 and will be verified by the local REAL-PANLAR representative of each country.

The aim of this implementation aims to foster institutional growth according to the needs of their region and the projection of the organization.

Accreditation process

Organizations wishing to be accredited as Centers of Excellence in Rheumatoid Arthritis in accordance with the general guidelines of the REAL-PANLAR project should check the web seminar on health quality management in rheumatoid arthritis available on the website established for this purpose.

Then they should review the requirements for each type of center of excellence according to the publication of the **Journal of Clinical Rheumatology**, May 2015, considering that they must meet at least MMC by filling out a self-assessment form provided for that purpose, and gather retrospectively information that can support the potential application to the accreditation process.

In case of not meeting any requirement, the website of REAL-PANLAR will be available to consult the implementation strategy of it, as it must comply with all the requirements when applying for accompaniment (15).

Once the organization or center completes the MMC to apply for accreditation, it should send a communication to CARPAR to start the procedure (Figure 2).

1. Application for accreditation

The center intending to be accredited must submit a formal visit request to CARPAR at least 6 months prior to the desired date of visit, after consulting with the local REAL-PANLAR representative in each country, who will evaluate compliance with the MMC.

If MMCs are not met, the CoE will reschedule a new visit by the local peer and request a return visit to CARPAR; the request will append a compliance or improvement plan for the shortcomings observed in the peer's prior verification. Once the application is reviewed, and it meets the requirements, CARPAR will schedule an official visit for verification/accreditation.

The applicant institution will periodically send the results of the indicators according to the type of center, until the verification / accreditation visit is scheduled.

Note: If the center does not meet the MMC, CARPAR may advise virtually in order to improve the shortcomings identified.

2. Evaluation/Verification visit

- Preparing documentation supporting each requirement depending on the type of CoE.
- Receiving the visit of the verification panel.
- Supporting compliance with the requirements as requested by the verification panel, so that it can check the recorded data in the format and to qualify as self-assessment as the process of accompaniment and verification.

A first assessment visit by the panel of verification will be made, where compliance with the standards defined in the format will be verified through auditing processes.

a) Standard CoE: 50 randomly selected medical records (MR), for which last year's records will be evaluated. It should be conducted in up to 36 hours. At least 80% of MR tested must meet *all criteria* to be accredited.

b) Optimal CoE: 75 randomly selected medical records, for which last year's records will be evaluated. It should be conducted in up to 36 hours. At least 85% of MR tested must meet *all criteria* to be accredited.

c) Model CoE: 100 randomly selected medical records. It should be conducted in up to 48 hours. At least 90% of MR tested must meet *all criteria* to be accredited.

3. Issuing the evaluation of the entity

The results of the visit will be based on the processing of the instruments used by the evaluators where the presence or absence of the criteria depending on the type of CoE will be verified. Favorable opinion will be issued when the CoE meets at least 80 (Standard), 85 (Optimal) and 90% (Model) of the requirements depending on the type of center. The formal initial accreditation as CoE will be valid for 3 years and thereafter for subsequent accreditations it will also be for 3 years.

- In cases where the results of evaluation of dossiers are 10% below the minimum percentage (Standard: 70-79%, Optimal: 75-84% and Model 80-89%), the center may request a return visit within 6 months, providing an improvement plan and expecting that they can correct the shortcomings noted.

If the observations are not resolved in the second evaluation visit, centers seeking accreditation must wait for a new nomination in two years.

4. Accreditation decision

The evaluation panel should deliver an in situ feedback after the end of the visit, and 4-8 weeks after the visit CARPAR should answer whether the applicant institution met the requirements for accreditation or not; within two weeks following the auditee center should manifest itself regarding its conformity with the evaluation, and in case of

disagreement it should state it in writing, and in this case CARPAR will have between 2 and 4 additional weeks for a final decision; this decision will be made by the CARPAR accrediting board, and it will be final.

5. Accreditation follow-up

The accreditation of the CoE in RA will be valid for three years. The center will apply for re-accreditation, which in subsequent periods will be for 3 years. CARPAR may make unannounced visits to the accredited CoE to assess compliance with accreditation criteria. If any difficulty is evident, CARPAR will assess the possibility of revoking the accreditation.

Next steps and scope for the implementation of the certification model (Accreditation)

1. Provides methodological support for centers or aspiring professionals to know the details of the accreditation.
2. Sensitizes those responsible for decision making in health and public policy on how to assess the quality of care for this disease.
3. It is expected to conduct a survey with national rheumatology scientific societies, in order to socialize the conditions of accreditation and explore centers and professionals who are possible candidates for the process.

DISCUSSION

The care of patients with chronic conditions lives different problematics related to diagnosis, treatment and monitoring of these diseases, which do not allow for a comprehensive approach. To this is added the low quality of the service, resulting in a poor use of resources and poor perception by the patient (16). In our case, patients with RA must receive care that can resolve in a timely and complete manner the difficulties that this disease causes, not just in the clinical sphere, but also socially, including these **five parameters: effective coverage of high quality treatment, accessibility, patient safety, best results in terms of health, and reducing the economic impact on the social and security systems (15).**

The CoE in RA are a response to these needs, allowing for taking the medical practice to its maximum expression, with the highest standards of quality in health, directly impacting the patient, as well as health economics (17).

These CoEs must be certified and endorsed by collegiate bodies and representatives of expert scientific communities on the subject such as associations of rheumatology and groups interested on excellence such as REAL-PANLAR, and ensure its implementation in any country that seeks to provide adequate care to patients with RA. Finally, the CoE could be academic formation spaces for rheumatologists where good clinical practices and standardization of (health care delivery) make part of the academic curriculum in centers where there are graduate rheumatology programs.

CONCLUSION

Finally we can conclude that after carrying out the consensus about the methodological approach for the accreditation process of Centers of Excellence in Rheumatoid Arthritis the following results were obtained:

1. Creation of a certification board for CoEs in RA - CARPAR
2. Definition of criteria to establish a CoE (Standard, Optimal and Model)
3. Generation of processes and procedures for the accreditation of CoEs in RA in LATAM.
4. Operational definitions related to accreditation of CoEs in RA were structured.
5. Is expected that REAL-PANLAR will evaluate the operation of the CoE in RA certification process annually, in order to continuously improve the evaluation process.

GLOSSARY

Rheumatologist: Health professional with a title of rheumatologist duly recognized by the local rheumatology society of each county.

Medical support staff: Professionals of medicine branches with proven studies that provide medical, physical and mental support for adequate integral care (general practitioner or internist, physiatrist, nursing personal, nutritionist, psychologist, occupational therapist, physiotherapist, etc.).

Laboratory: Clinical laboratories in a reference center should have the ability to process routine and immunological tests (including as a minimum ANAs, anti DNA, ENAS, anti CCP, rheumatoid factor and other tests) for a proper diagnosis of the patient.

Radiology center: The radiological reference center should have the capacity to process conventional and high - definition images digitally.

Medical Records: The records must be available physically or ideally in digital form for later audit.

Joint Count: The clinician should document the number of tender and swollen joints at each visit the patient receives.

Indices of Disease Activity: To measure disease activity any instrument of clinimetry intended for this purpose (DAS28, DAS44, ACR20, 50 or 70, SDAI, CDAI) may be used, including joint counts.

Indices of Functionality: HAQ will be used to measure the functional capacity of patients (18).

Adherence to Treat to Target (T2T): It will be defined as clinical disease management based on the results of the clinimetry presented, e.g. DAS28 with high disease activity (> 5.1) or a similar index: must have a change (improvement) in treatment and associated with track 1 - 1.5 months, with some exceptions such as forgetfulness in taking the medication, illness, hospitalization or other conditions of patients to justify the non-adherence to treatment and thus deterioration in disease activity. DAS28 with moderate disease activity (> 3.2) or similar index: must have a change in treatment and follow-up associated with a 1.5-2.5 months, unless the same exceptions described in the previous section. DAS28 in remission or low disease activity (< 3.2) or similar activity index: usually implies no change in treatment and patient will be followed-up between 2 to 4 months (19, 20).

Recommendation 10 of T2T: Patients should be informed about treatment goals and processes to achieve, with shared decisions with the attending physician (20).

Continuing Medical Education Program: It is an educational process that involves continuous improvement and training of physicians working at center in a respective pathology such RA.

Patient Education Program: A center that treats patients with RA should have a structured learning process aimed to patients, which teach about different aspects of the disease (21).

Clinical Management Protocol: An accredited center must have a clinical protocol of sequential operation and medical taking decisions based on levels of scientific evidence.

Ultrasound: A center that aspires to be accredited as CoE model type in RA must have a device musculoskeletal ultrasound, managed by rheumatologist or radiologist and which should be involved in the diagnostic process, clinical monitoring and research.

Scientific publication: Product of knowledge generation resulting of a research project that originates from the experience of the CoE, which appears indexed in one of the largest databases of journals: PubMed, MEDLINE, EMBASE, Scopus, lilacs etc.

Participation in academic events: Dissemination of results of own research in academic events, such as posters, oral presentations, etc.

Report of adverse events: A center of model type must have a pharmacovigilance system to allow continuous reporting of adverse events and their respective correction as well as the respective indices.

Patients report of low activity or remission: In the center that aspires to be accredited as CoE model type, account should be reporting rates of low activity or remission of RA, susceptible of improvement over time.

Satisfaction surveys: In the center that aspires to be accredited as CoE model type, account should be satisfaction surveys of users that are measurable and susceptible of improvement over time.

Adherence Program: In the center that aspires to be accredited as CoE model type, must have a program adherence for patients, both the model itself as medication.

Interest Conflict

The authors do not declare conflicts of interest regarding this paper.

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Tables and figures

Table 1. Requirements for the accreditation of a CoE

Criterion		Type of CoE		
		STANDARD	OPTIMUM	MODEL
STRUCTURE	Rheumatologist	<i>X (one)</i>	<i>X (two)</i>	<i>X (three)</i>
	Health Professional (nursing, dietician, physiatrist, occupational therapy and psychology).	X	X	X
	Medical history (digital)	X	X	X
	Access to routine clinical laboratory and immunological tests (ANA, ENA, Anti CCP, FR)	X	X	X
	Presence of a radiological support center.	X	X	X
PROCESS	Conducting joint counts	X	X	X
	Measurement of disease activity (DAS28, SDAI, CDAI)	X	X	X
	T2T application and / or a clinical practice guideline (disease activity)	X	X	X
	Realization of functional capacity questionnaire (HAQ)	X	X	X
	Possession of a medical education program for doctors and related specialties.		X	X
	Possession of an education program on the disease for patients.		X	X
	Workshops, symposia, clinical meetings or medical boards		X	X
	Presence of ultrasound equipment driven rheumatologist.			X
	Patient satisfaction surveys			X

RESULT	At least two research products per year (presentation events academics- publishing articles)			X
	Existence of low rates of disease activity or remission of RA			X
	Drug-monitoring involving measuring adverse events			X
	Implementation of mechanisms for improving adherence to treatment (measurable)			X

Figure 1. Accrediting body - PANLAR

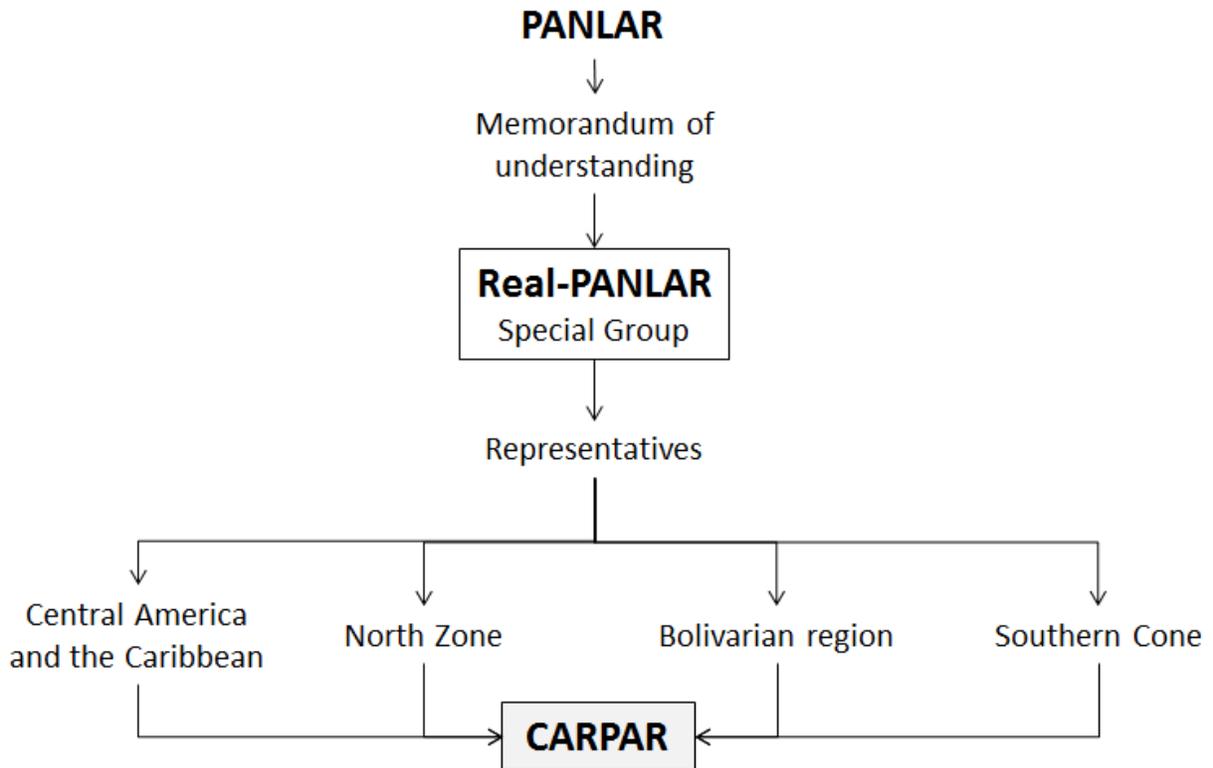


Figure 2. Procedure for accreditation of CoE

