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# Applying the 2019 EULAR/ACR lupus criteria to patients from an established cohort: a Latin American perspective

Guillermo J Pons-Estel ,[1,2] Manuel Francisco Ugarte-Gil ,[3,4] Guillermina B Harvey,[5] Daniel Wojdyla,[5] Rosana Quintana,[1,2] Verónica Saurit,[6] Enrique R Soriano,[7] Eloisa Bonfa,[8] Loreto Massardo,[9] Mario Cardiel,[10] Luis M Vila,[11] Russell Griffin,[12] Bernardo A Pons-Estel,[1] Graciela S Alarcón,[13] On behalf of the Grupo Latino Americano De Estudio de Lupus (GLADEL)

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GJP-E and MFU-G contributed equally.

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For numbered affiliations see end of article.

**Correspondence to**
Dr Guillermo J Pons-Estel; gponsestel@hotmail.com

## ABSTRACT

**Objective** To evaluate the performance of the 2019 European League Against Rheumatism (EULAR)/American College of Rheumatology (ACR) systemic lupus erythematosus (SLE) criteria in terms of earlier patients' classification in comparison to the 1982/1997 ACR or the 2012 Systemic Lupus International Collaborating Clinics (SLICC) criteria.

**Materials and methods** Patients from a Latin America, multiethnic, multicentre cohort, where SLE was defined using the physicians' diagnosis, were included. To calculate the sensitivity of the 2019 EULAR/ACR criteria, the 1982/1997 ACR criteria were considered the gold standard. Additionally, comparison of the 1982/1997 ACR criteria and the 2012 SLICC criteria with the 2019 EULAR/ACR criteria was performed.

**Results** The sensitivity of the 2019 EULAR/ACR criteria when compared with the 1982/1997 ACR criteria as the gold standard was 91.3%. This new set of criteria allowed an earlier SLE patient classification in 7.4% (mean 0.67 years) and 0.6% (mean 1.47 years) than the 1982/1997 ACR and the 2012 SLICC criteria, respectively. Patients accruing the 2019 EULAR/ACR earlier than the 1982/1997 ACR criteria were more likely to have high anti-dsDNA titres; those accruing them later were less likely to have mucocutaneous and joint manifestations; this was not observed when comparing them with the 2012 SLICC criteria.

**Conclusions** The 2019 EULAR/ACR criteria classified earlier only a small proportion of Latin America patients than with the two other criteria sets in real-life clinical practice scenarios. Further studies in different patient populations are needed before these new criteria are adopted worldwide.

## Key messages

### What is already known about this subject?

- Criteria are needed so that patients with systemic lupus erythematosus (SLE) identified and selected for a given study share clinical and laboratory features.
- The overarching goal of the 2019 EULAR/American College of Rheumatology (ACR) SLE criteria is to be able to classify patients as having lupus earlier than with the ACR or the Systemic Lupus International Collaborating Clinics criteria and be able to include them in randomised clinical trials and/or longitudinal observational studies.

### What does this study add?

- In this multiethnic lupus cohort, these new criteria did not achieve the goal of classifying patients earlier than with the two previous criteria sets.

### How might this impact on clinical practice?

- Our work reinforces the notion that these new criteria need to be examined in various populations, with different degrees of disease activity, particularly in patients with early disease; this should be done not only in Latin America but across the world.

## INTRODUCTION

Clinicians rely on their experience and clinical acumen to diagnose and treat patients with lupus. However, for the conduct of clinical studies, being those observational or randomised clinical trials (RCTs), criteria are needed so that patients identified and selected for a given study share defined clinical and laboratory features. Establishing criteria that have good psychometric properties are crucial. Although the 1982 American College of Rheumatology (ACR) criteria,[1] modified in 1997 although never validated,[2] have been widely used worldwide, that is not to say that they are perfect. A major effort to develop new criteria was marshalled by the Systemic Lupus International Collaborating Clinics (SLICC) in the early 2000; this effort resulted in the 2012 SLICC criteria, which have been used as an alternative to the ACR criteria or in conjunction with them.[3] More recently, the European League Against

Rheumatism (EULAR) and the ACR have jointly developed a new set of criteria using a four-phase process: (1) Determining the sensitivity and specificity of AntiNuclear Antibodie (ANA) positivity and establishing it as the entry point and list all possible clinical manifestations of lupus, (2) Item reduction using a nominal group technique and comparing these manifestations in lupus patients and patients with related conditions. In this phase, a group of German patients with early lupus responded to a survey about their clinical manifestations; at the end of this phase, 21 manifestations remained. (3) Weighting of the 21 items selected in phase 2 grouped in two domains: clinical and immunological, and (4) Testing the new criteria in large independent lupus cohorts.[4–9] There are two main differences between this set of criteria and the previous ones: (1) The premise that to enter the classification criteria, a patient had to be ANA positive and (2) That different criteria exert a different weight towards its fulfilment; the overarching goal of these new criteria is to be able to classify patients as having lupus earlier than with the 1982/1997 ACR or the 2012 SLICC criteria and be able to include them in RCTs and/or longitudinal observational studies. We have now examined whether in fact patients from uncontrolled real-life clinical settings would be classified earlier using the 2019 EULAR/ACR than the 1982/1997 ACR or the 2012 SLICC criteria; to this end, we have used the database from a large, multiethnic, multinational Latin America lupus cohort.

## PATIENTS AND METHODS

The GLADEL (for Grupo Latino Americano De Estudio de Lupus or Latin American Group for the Study of Lupus) cohort have been amply described in the literature.[10 11] Patients were recruited into GLADEL based on the physicians' diagnosis of lupus; these physicians had experience in systemic lupus erythematosus (SLE) (they had an outstanding academic profile, were practising at referral centres with specialised lupus clinics and rheumatology training programmes). Nevertheless, most of these patients (95.5%) also fulfilled the 1982/1997 ACR criteria. We must point out that of all the clinical and laboratory manifestations included on the new 2019 EULAR/ACR criteria, only delirium, had not been recorded in this cohort's database; therefore, it could not be included in these analyses. The clinical and laboratory variables from all cohort patients were measured in all of them at the time of their entry into the cohort and every 6 months thereafter. Investigators were asked to establish precisely the dates of disease onset, diagnosis and fulfilment of ACR SLE criteria. It should be noted, however, that being this an inception cohort (within 2 years of diagnosis) patients included did not require to fulfil the 1982/1997 ACR classification criteria as an entry point into the cohort.

We have now compared the 1982/1997 ACR criteria and the 2012 SLICC criteria with the 2019 EULAR/ACR criteria in this cohort. In all cases, the goal was to determine which set of criteria would allow for an earlier patient classification. Sensitivity was also calculated for the 2019 EULAR/ACR criteria, using the 1982/1997 ACR criteria as the gold standard. Alternative analyses were performed including only those patients with complete clinical and laboratory data at all visits.

Patients were not involved in the design, execution or writing of this manuscript as the study was conducted using data already available in this cohort database.

The statistical analyses were performed using SAS software, V.9.1.3 (SAS). Categorical variables were compared using $\chi^2$ and Freeman-Halton test while continuous variables were compared with Wilcoxon test. A $p<0.05$ was set as the level of statistical significance.

## RESULTS

For these analyses, of the 1480 patients included in the GLADEL cohort, as classified by experienced physicians, 433 were excluded from these analyses; 49 of them, because they had a negative ANA, 121 because their ANA titre was <80 and 263 because the titre had not been recorded. In addition, 68 patients (6.5%) were excluded because they did not meet the 2019 EULAR/ACR criteria despite the fact that 0.46 years had elapsed between the time they met the 1982/1997 ACR and the 2012 SLICC criteria and the time they entered the GLADEL cohort. Additionally, 23 patients were excluded because of missing dates to fulfil the 1982/1997 ACR; for the 2012 SLICC, only one additional patient was excluded.

Therefore, 956 patients with available fulfilment dates for the ACR 1982/1997 (table 1) and the 978 patients with fulfilment dates for the 2012 SLICC (table 2) were included. We found no differences in terms of ethnicity and gender between included and excluded patients; however, the excluded patients were older (mean±SD: 35.6±14.1 vs 29.8±12.4) and had a lower SLE Disease Activity Index (SLEDAI) score (5.5±5.1 vs 10.7±8.0).

The sensitivity of the 2019 EULAR/ACR criteria when compared with the 1982/1997 ACR as the gold standard was 91.3%.

Of the 956 and 978 GLADEL patients, the large majority, 556 (58.2%) and 692 (70.8%) met the 2019 EULAR/ACR criteria at the same time that the 1982/1997 ACR or the 2012 SLICC criteria, while 71 and 6 (7.4%, mean 0.67 years and 0.6%, mean 1.47 years) met them earlier and 329 and 280 (34.4%, mean 1.06 years and 28.6%, mean 1.24 years) met them later, respectively. Figure 1 depicts the Kaplan-Meier survival curve for the estimated proportion of patients with SLE who met the 2019 EULAR/ACR during the course of the disease. Among patients classified earlier with the 2019 EULAR/ACR criteria than with the 1982/1997 ACR criteria, anti-dsDNA antibodies were more frequent than in those classified at the same time or later with this set of criteria. Among those patients who were classified later with 2019 EULAR/ACR than with the 1982/1997 ACR criteria, acute cutaneous lupus, oral ulcers and synovitis were more frequent than in those

**Table 1** Characteristics at the time of 2019 EULAR/ACR-based classification in the GLADEL cohort patients classified at the same time, earlier, or later than based on the 1982/1997 ACR criteria

| | At EULAR/ACR classification | EULAR/ACR classification at the Same time, (%) | EULAR/ACR classification earlier, (%) | EULAR/ACR classification later, (%) | |
|---|---|---|---|---|---|
| | n=956 | n=556 (58.2) | n=71 (7.4) | n=329 (34.4) | P value |
| Demographic | | | | | |
| Ethnicity, n (%) | | | | | <0.001 |
| Mestizos | 368 (38.5) | 190 (34.2) | 43 (61.4) | 135 (41.2) | |
| Caucasian | 464 (48.5) | 289 (52.0) | 21 (30.0) | 154 (47.0) | |
| African Latin American | 103 (10.8) | 68 (12.2) | 6 (8.6) | 29 (8.8) | |
| Others | 19 (2.0) | 9 (1.6) | 0 (0.0) | 10 (3.1) | |
| Gender, n (%) | | | | | 0.450 |
| Female | 860 (90.0) | 497 (89.4) | 62 (87.3) | 301 (91.5) | |
| Male | 96 (10.0) | 59 (10.6) | 9 (12.7) | 28 (8.5) | |
| Age at enrolment, mean (SD), years | 29.8 (12.4) | 29.8 (12.8) | 30.4 (11.6) | 29.5 (11.7) | 0.858 |
| Clinical | | | | | |
| SLEDAI score at enrolment, mean (SD) | 10.7 (8.0) | 10.9 (7.9) | 9.3 (7.7) | 10.7 (8.2) | 0.350 |
| ACR/EULAR criteria | | | | | |
| Clinical domains | | | | | |
| Fever* | 64.6 | 64.4 | 59.2 | 66.3 | 0.515 |
| Acute cutaneous (or malar rash)* | 69.0 | 65.5 | 54.9 | 78.1 | <0.001 |
| Subacute cutaneous lupus or discoid rash* | 4.3 | 5.0 | 2.8 | 3.3 | 0.397 |
| Oral ulcers* | 45.4 | 41.6 | 36.6 | 53.8 | 0.001 |
| Non-scarring alopecia* | 64.9 | 65.7 | 60.6 | 64.4 | 0.687 |
| Synovitis* | 84.6 | 83.1 | 78.9 | 88.5 | 0.039 |
| Seizures* | 10.3 | 10.1 | 8.5 | 10.9 | 0.802 |
| Psychosis* | 7.6 | 6.7 | 9.9 | 8.8 | 0.386 |
| Delirium* | NA | NA | NA | NA | NA |
| Acute pericarditis* | 16.6 | 16.6 | 16.9 | 16.7 | 0.996 |
| Pleural or pericardial effusion* | 31.4 | 30.9 | 26.8 | 33.1 | 0.543 |
| Thrombocytopaenia* | 24.3 | 24.1 | 25.4 | 24.3 | 0.973 |
| Autoimmune hemolysis* | 13.6 | 16.7 | 7.0 | 9.7 | 0.003 |
| Leucopaenia* | 56.7 | 55.8 | 53.5 | 59.0 | 0.554 |
| Proteinuria* | 48.3 | 47.5 | 50.7 | 49.2 | 0.807 |
| Renal biopsy II or V* | 7.6 | 6.5 | 8.5 | 9.4 | 0.270 |
| Renal biopsy III or IV* | 19.1 | 19.2 | 21.1 | 18.5 | 0.876 |
| Immunologic | | | | | |
| aCL >40 or LAC (+)†* | 59.5 | 59.1 | 59.6 | 60.1 | 0.973 |
| Low C3 or C4‡* | 72.9 | 74.0 | 75.9 | 70.3 | 0.498 |
| Low C3 and C4‡* | 55.3 | 57.6 | 56.9 | 51.0 | 0.218 |
| Anti-Sm§* | 48.6 | 47.9 | 44.4 | 50.6 | 0.747 |
| Anti-dsDNA¶* | 74.9 | 75.5 | 87.3 | 71.1 | 0.023 |

Categorical variables were compared using $X^2$ test and Freeman-Halton test while continuous variables were compared with Wilcoxon test.
*Values are depicted as percentages.
†Data available in 622 patients.
‡Data available in 767 patients.
§Data available in 517 patients.
¶Data available in 863 patients.
aCL, anticardiolipin antibodies; ACR, American College of Rheumatology; GLADEL, Grupo Latino Americano De Estudio de Lupus; LAC, lupus anticoagulant; NA, not available; SLEDAI, Systemic Lupus Erythematosus Disease Activity Index.

classified earlier or at the same time. Because of the fact that very few patients classified as having lupus earlier with the 2019 EULAR/ACR criteria than with the 2012 SLICC criteria firm conclusions cannot be drawn about these patients' characteristics. Mucocutaneous manifestations and synovitis, however, tended to occur at the same

**Table 2** Characteristics at the time of 2019 EULAR/ACR-based classification in the GLADEL cohort patients classified at the same time, earlier or later than based on the 2012 SLICC criteria

| | At EULAR/ACR classification | EULAR/ACR classification at the same time, (%) | EULAR/ACR classification earlier, (%) | EULAR/ACR classification later, (%) | |
|---|---|---|---|---|---|
| | n=978 | n=692 (70.8) | n=6 (0.6) | n=280 (28.6) | P value |
| Demographic | | | | | |
| Ethnicity, n (%) | | | | | |
| Mestizos | 377 (38.5) | 249 (35.9) | 3 (50.0) | 126 (44.8) | 0.027 |
| Caucasian | 478 (48.9) | 347 (50.2) | 3 (50.0) | 127 (45.5) | |
| African Latin American | 105 (10.7) | 85 (12.3) | 0 (0.0) | 19 (6.8) | |
| Others | 18 (1.9) | 11 (1.6) | 0 (0.0) | 8 (2.9) | |
| Gender, n (%) | | | | | 0.654 |
| Female | 880 (90.0) | 622 (89.9) | 5 (83.3) | 253 (90.4) | |
| Male | 98 (10.0) | 70 (10.1) | 1 (16.7) | 27 (9.6) | |
| Age at enrolment, mean (SD) | 29.9 (12.5) | 29.8 (12.5) | 24.5 (8.0) | 30.3 (12.5) | 0.472 |
| Clinical | | | | | |
| SLEDAI score at enrolment, mean (SD) | 10.6 (8.0) | 11.1 (8.3) | 7.6 (6.0) | 9.5 (7.1) | 0.025 |
| ACR/EULAR criteria | | | | | |
| Clinical domains | | | | | |
| Fever* | 64.2 | 66.5 | 66.7 | 58.6 | 0.060 |
| Acute cutaneous (or malar rash)* | 67.7 | 70.1 | 50.0 | 62.1 | 0.028 |
| Subacute cutaneous lupus or discoid rash* | 4.3 | 4.6 | 16.7 | 3.2 | 0.145 |
| Oral ulcers* | 44.4 | 44.9 | 0.0 | 43.9 | 0.084 |
| Non-scarring alopecia* | 64.0 | 64.7 | 0.0 | 63.6 | 0.005 |
| Synovitis* | 83.3 | 84.1 | 66.7 | 81.8 | 0.244 |
| Seizures* | 10.0 | 10.6 | 0.0 | 8.9 | 0.726 |
| Psychosis* | 7.6 | 7.1 | 0.0 | 8.9 | 0.595 |
| Delirium | NA | NA | NA | NA | NA |
| Acute pericarditis* | 16.5 | 17.6 | 0.0 | 13.9 | 0.240 |
| Pleural or pericardial effusion* | 30.9 | 32.9 | 0.0 | 26.4 | 0.036 |
| Thrombocytopaenia* | 24.5 | 25.3 | 16.7 | 22.9 | 0.694 |
| Autoimmune hemolysis* | 13.6 | 14.9 | 0.0 | 10.7 | 0.154 |
| Leucopaenia* | 56.3 | 54.6 | 0.0 | 61.8 | 0.002 |
| Proteinuria* | 47.8 | 49.0 | 33.3 | 45.0 | 0.425 |
| Renal biopsy II or V* | 7.7 | 7.1 | 0.0 | 9.6 | 0.321 |
| Renal biopsy III or IV* | 19.0 | 20.7 | 16.7 | 15.0 | 0.099 |
| Immunlogic | | | | | |
| aCL >40 or LAC (+)†* | 58.9 | 56.4 | 25.0 | 65.5 | 0.028 |
| Low C3 or C4‡* | 72.9 | 74.3 | 100.0 | 68.9 | 0.118 |
| Low C3 and C4‡* | 54.8 | 58.8 | 66.7 | 45.1 | 0.001 |
| Anti-Sm§* | 48.8 | 49.9 | 66.7 | 45.5 | 0.533 |
| Anti-dsDNA¶* | 74.5 | 77.5 | 40.0 | 67.7 | 0.002 |

Categorical variables were compared using Freeman-Halton test while continuous variables were compared with Wilcoxon test.
*Values are depicted as percentages.
†Data available in 635 patients.
‡Data available in 785 patients.
§Data available in 527 patients.
¶Data available in 879 patients.
aCL, anticardiolipin antibodies; ACR, American College of Rheumatology; GLADEL, Grupo Latino Americano De Estudio de Lupus; LAC, lupus anticoagulant; NA, not available; SLEDAI, Systemic Lupus Erythematosus Disease Activity Index; SLICC, Systemic Lupus International Collaborating Clinics.

time or later with the 2019 EULAR/ACR than with the 2012 SLICC criteria in this cohort. Patients achieving the 2019 EULAR/ACR criteria later were more likely to be Caucasian, whereas Mestizos tended to be classified earlier, but age and gender were comparable among all groups. Disease activity as measured by the SLEDAI was

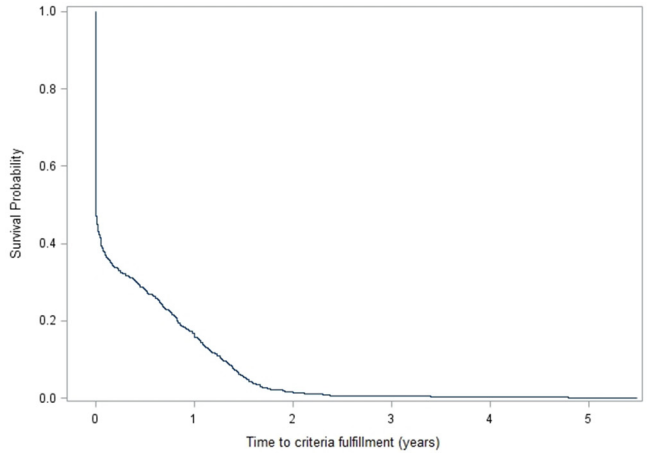


**Figure 1** Kaplan-Meier survival curve depicting the estimated probability of fulfilling the 2019 EULAR/ACR during the course of the disease (n=979). ACR, American College of Rheumatology.

somewhat lower in those patients classified earlier. These data are depicted in tables 1 and 2. Alternative analyses including only patients with complete data for all visits examined were performed; there were 523 out of 956 and 532 out of 978 patients for the 2019 EULAR/ACR and 2012 SLICC, respectively. The large majority, 301 (57.6%) and 369 (69.4%) met the 2019 EULAR/ACR criteria at the same time that the 1982/1997 ACR or the 2012 SLICC criteria, while 42 and 3 (8.0% and 0.6%) met them earlier and 180 and 160 (34.4% and 30.0%) met them later, respectively (data not shown).

## DISCUSSION

A major and concerted effort has been made by EULAR and the ACR over the last several years to develop a more efficient set of classification criteria for patients with SLE; however, it remains to be known how these new criteria will perform in real-life clinical settings in different geographical regions and ethnic groups across the world. In this study, performed in a Latin America multiethnic, multinational cohort, the 2019 EULAR/ACR criteria apparently allowed an earlier classification of patients with SLE, only in a relatively small proportion of them, compared with the 1982/1997 ACR and the 2012 SLICC criteria: only 7.4% and 0.6% patients were classified earlier using the 2019 EULAR/ACR criteria than 1982/1997 ACR and the 2012 SLICC criteria, respectively. On the other hand, the sensitivity of these criteria was not as high as expected; in fact, between 6.6% and 15.3% of patients did not achieve these new criteria, depending on which set of patients was used. Nevertheless, we need to take into consideration that GLADEL did not include delirium, one of the three clinical manifestations (the one with less weight, that equals two points) of the neuropsychiatric domain noted in the new criteria; this may have attempted against their performance, although this manifestation occurs rather infrequently in lupus patients, in general; so the effect of lacking this information is, with all probability, negligible. In addition, in this cohort, laboratory tests were obtained as felt to be indicated by the treating physicians; thus, if a test was not indicated/obtained, the assumption made was that it was negative, which may not have been the case. Therefore, the true performance of these criteria will have to be examined in data gathered in a longitudinal manner by different investigators across the world rather than using existing databases.

No consistent pattern was found in terms of patients from a particular ethnic group being more likely to be classified earlier or later with the 2019 EULAR/ACR criteria with the exception of the Mestizo patients who tended to be classified earlier and Caucasian patients later. Likewise, no clear pattern emerged in terms of earlier classification as a function of age and gender.

When the clinical manifestations were taken into account, patients who achieved the 2019 EULAR/ACR criteria earlier than the 1982/1997 ACR, had a lower frequency of milder disease manifestations (like mucocutaneous and articular) and tended to have a higher frequency of anti-dsDNA antibodies, suggesting these criteria could be quite useful in subsets of patients with more severe disease. On the other hand, no clinical or laboratory features emerged as being clearly associated to the earlier identification of lupus by the 2019 EULAR/ACR criteria.

The 2019 EULAR/ACR criteria refer to the interdependency of items, proposing that some criteria might cluster into 'buckets'; this issue has not been previously addressed in any SLE classification criteria set. However, this set of criteria did not achieve the goal of classifying patients from this cohort as having lupus earlier than with the 1982/1997 ACR or the 2012 SLICC criteria. This may be partly due to the limitations listed above or to the fact that these criteria as well as other previously published, consider lupus as one disease; with advances in our understanding of the pathophysiological molecular basis of this disease manifestations, it is becoming clear that SLE is a syndrome with patients clustering into different groups[12–14]; defining lupus using this molecular approach maybe more rewarding but we are not there yet; moreover, such tools may not be readily available across the world.

Our study has some limitations. First, the patients studied were mostly adults so whether these new criteria perform differently and better in paediatric lupus patients cannot be stated with certainty. Second, we were not able to determine the specificity of these classification criteria as we did not have access to a control group of patients without lupus; furthermore, the use of expert-based opinion to define a clinical condition, as well as the possibility that not all the manifestations listed in the 2019 EULAR/ACR criteria were recorded in this cohort, prevent us from reaching firmer conclusions. Third, as noted above one clinical variable from the new criteria (delirium) was not recorded; in addition, some immunological variables were not obtained as already noted; so, this may partially explain why in this real-life clinical setting only a small number of our cohort patients were classified earlier with the 2019 EULAR/ACR

criteria when compared with the other sets. Finally, the date at which each criterion manifestation had occurred was based on the information available; it is possible that these dates may not have the precision that could had been derived from obtaining these data with the specific purpose of assessing all three sets of criteria.

In short, we found that the 2019 EULAR/ACR criteria did not achieve the goal of classifying our patients earlier than with the two previous criteria sets. While we appreciate the incredible effort that has taken the lupus community this far in terms of classifying lupus patients, we realise these new criteria need to be examined in various populations, with different degrees of disease activity, particularly in patients with early disease; this should be done not only in Latin America but across the world. Only then, these criteria could be used in intervention trials and longitudinal observational studies.

**Author affiliations**
[1]Centro Regional de Enfermedades Autoinmunes y Reumáticas (GO-CREAR), Rosario, Santa Fe, Argentina
[2]Servicio de Reumatología, Hospital Provincial de Rosario, Rosario, Santa Fe, Argentina
[3]School of Medicine, Universidad Cientifica del Sur, Lima, Peru
[4]Servicio de Reumatología, Hospital Nacional Guillermo Almenara Irigoyen. EsSalud, Lima, Peru
[5]Escuela de Estadística, Facultad de Ciencias Económicas y Estadística, Universidad Nacional de Rosario, Rosario, Argentina
[6]Servicio de Reumatología, Hospital Privado Universitario de Córdoba, Córdoba, Córdoba, Argentina
[7]Rheumatology, Hospital Italiano de Buenos Aires, Buenos Aires, Argentina
[8]Rheumatology, Faculdade de Medicina da Universidade de São Paulo-USP, São Paulo, SP, Brazil
[9]Centro de Biología Celular y Biomedicina, Universidad San Sebastián, Santiago, Chile
[10]Centro de Investigacion Clinica de Morelia, Morelia, Michoacán, Mexico
[11]Division of Rheumatology, University of Puerto Rico, San Juan, San Juan, Puerto Rico
[12]Epidemiology, University of Alabama at Birmingham, Birmingham, Alabama, USA
[13]Department of Medicine, Division of Clinical Immunology and Rheumatology, School of Medicine, The University of Alabama, Birmingham, Alabama, USA

**Twitter** Guillermo J Pons-Estel @gponsestel and Manuel Francisco Ugarte-Gil @mugartegil

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**ORCID iDs**
Guillermo J Pons-Estel http://orcid.org/0000-0002-0647-929X
Manuel Francisco Ugarte-Gil http://orcid.org/0000-0003-1728-1999

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