Response to: 'Correspondence on 'Performance of the 2019 EULAR/ACR classification criteria for systemic lupus erythematosus in early disease, across sexes and ethnicities" by Rönnelid *et al*

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We thank Rönnelid *et al* for their comments on our paper, 'Performance of the 2019 EULAR/ACR classification criteria for systemic lupus erythematosus in early disease, across sexes, and ethnicities.'[1]

In 2019, the authors comparatively evaluated the 'diagnostic accuracy' of the 2019 European League Against Rheumatism (EULAR)/American College of Rheumatology (ACR) systemic lupus erythematosus (SLE) criteria[2 3] against the 2012 Systemic Lupus International Collaborating Clinics (SLICC) criteria. In referring to their paper,[4] we stated that it is inappropriate to evaluate the 2019 EULAR/ACR criteria as diagnostic criteria. Rönnelid *et al* now point out that diagnostic use of the criteria was not their intention. They make the point that they used the term diagnostic, as diagnostic sensitivity and diagnostic specificity.[1]

While we agree that these terms may correct, there still is concern that they will be misunderstood by many readers who conflate classification and diagnostic criteria. Indeed, we have misunderstood the terminology in the authors 2019 paper,[4] interpreting their statements in the context of diagnostic criteria.

As Landewe and van der Heijde discuss, being fastidious about the word diagnostic may seem trivial.[5] However, in the rheumatology community, classification criteria are mistakenly used as diagnostic criteria. Both the ACR and EULAR therefore make a clear distinction between classification and diagnostic criteria.[6] Classification criteria are intended to identify homogeneous patients for inclusion into clinical trials and observational studies.[7 8] This is particularly helpful for the study of rheumatic diseases with heterogeneous manifestations.[9] Classification criteria are expected to have higher sensitivity and possibly lower specificity, as they are designed to be more broadly applicable to an entire group of patients who look similar.[7 10]

In contrast, diagnosis remains in the realm of physician judgement, with legal, financial and treatment implications. Universal diagnostic criteria cannot be used for making diagnosis due to variable disease prevalence in different geographical areas, race and ethnicities.[6] Aggarwal *et al* have delineated these and other fundamental concerns related to diagnostic criteria in rheumatology.[6] Consequently, neither the ACR nor EULAR endorse diagnostic criteria.[6] Adding 'diagnostic' to sensitivity and specificity may therefore lead to uncertainty with potentially deleterious ramifications for patient care.[5]

We also thank the authors for expanding on issues related to the use of antinuclear antibodies (ANA) as an entry criterion for SLE classification. Using both data from a systematic review and metaregression of 12 542 patients with SLE and 7539 controls,[11] followed by expert panel consensus,[12] and subsequent validation,[2] the literature-based definition of ANA at a titre of ≥1:80 on HEp-2 cells was amended by 'or an equivalent positive test'. This entry criterion was designed to increase sensitivity, with ANA specificity being suboptimal even under the best of circumstances. The inclusion of the phrase 'or an equivalent positive test' was our attempt to address several issues, including the one the authors raise.

We appreciate the commentary of Rönnelid *et al* for highlighting these complex and important issues, and for inviting further academic discussion.

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