AMERICAN COLLEGE OF RHEUMATOLOGY
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ACR Criteria Development Checklists *(updated March 2018)*

Classification criteria development checklist:

1. Will a comprehensive list of possible criteria be considered (content validity)?
2. Will each of the potential criteria be reliable (reproducible), precise in its measurement, easy to measure, and clinically sensible?
3. Are the potential criteria redundant (i.e., highly correlated)? Will this be assessed?
4. Selection of cases (patients considered to have the condition of interest):
    a. Will cases be chosen across the spectrum of disease severity?
    b. If the criteria are to be used for epidemiologic studies, will both clinical and community cases be included?
5. Selection of controls (patients considered not to have the condition of interest):
    a. Will the controls be chosen with a view to the intended purpose of the criteria, i.e., to distinguish individuals with disease from those without disease versus to distinguish individuals with a particular rheumatic disease from individuals with other diseases? Ideally, multiple control groups will be used.
6. Will at least 100 cases and 100 controls be chosen?
7. For each individual criterion, and for combinations of criteria, will the sensitivity and specificity for detecting and ruling out the disease of interest be calculated (construct validity, convergent and divergent validity)? Will these results, together with clinical opinion, be used to reduce the number of criteria for inclusion?
8. Are the criteria to be included those with the greatest content and construct validity? How will this be demonstrated?
9. Will acceptable statistical approaches be used to create the classification criteria from the reduced number of criteria?
10. Will the final classification criteria be validated in different samples of cases and controls? How will those other samples be chosen? NOTE: The ACR requires project proposals to include a plan for validation of proposed criteria in an independent dataset that includes both cases and controls.

Response criteria or disease severity/damage criteria development checklist:

1. Will a comprehensive list of criteria for potential inclusion be developed (content validity)? How?
2. Will each of the chosen elements be reliable (reproducible), precise, easy to measure, and clinically sensible?
3. Selection of cases (patients with the given disease):
    a. Will cases be chosen across the spectrum of disease severity or damage?
    b. If the criteria are to be used for epidemiologic studies, will both clinical and community cases be included?
4. Will at least 200 cases be chosen?
5. Will the chosen criteria be redundant (i.e., highly correlated)? How will this be examined?
6. Will an appropriate statistical method be used to identify the number of factors or constructs represented by the various criteria?
7. Will an appropriate statistical approach be used to determine which

factors/elements differentiate patients across the spectrum of disease severity?

8. Will the final response criteria or disease severity/damage criteria be validated in an independent sample? NOTE: The ACR requires project proposals to include a plan for validation of proposed criteria in an independent dataset that includes both cases and controls. For response criteria, however, “provisional endorsement” may be given in the instance that the investigators can demonstrate there are no available clinical trial data suitable for external validation, with the expectation that external validation will occur as trial data becomes available. The investigators will then provide the externally validated criteria for full ACR approval/endorsement.