The study included patients (n = 1,002) with local and widespread pain from 55 centers. Using the 1990 American College of Rheumatology (ACR) FM criteria, including the assessment of tender points, the patients were diagnosed as having FM (Wolfe F, Smythe HA, Yunus MB, Bennett RM, Bombardier C, Goldenberg DL, et al. The American College of Rheumatology 1990 criteria for the classification of fibromyalgia: report of the Multicenter Criteria Committee. Arthritis Rheum 1990;33:160–72). Widespread pain was assessed by body pain drawing, and extensive questionnaires were applied. After a series of analyses, Wolfe et al concluded that a widespread pain index was the best predictor of FM. When this index was excluded from the analysis, key predictors of FM were nonrefreshing sleep, fatigue, cognitive difficulties, and a host of somatic symptoms. These 4 variables were then combined into a symptom severity scale, which ranged from 0–12. This symptom severity scale highly correlated with both the tender point count and the widespread pain index. The combination of the symptom severity scale and the widespread pain index identified 80.9% of the FM cases previously diagnosed by the 1990 ACR criteria. Furthermore, the symptom severity scale was useful for identifying previously diagnosed FM in patients who no longer satisfied ACR criteria. In phase 2 of their study, Wolfe et al collected the widespread pain index and symptom severity scale scores and reported that they performed well for diagnosing FM.

Wolfe and colleagues promote new diagnostic criteria that are almost as good (80% correct classification) as the previous criteria. The irony of this approach is that these 1990 ACR criteria had been previously disparaged by the same authors. Therefore, it is hard to consider this an advance of the clinical science.

Wolfe and colleagues are to be commended for this attempt at simplifying the diagnostic criteria for FM for general practitioners and specialists alike. Most of us will agree that the 1990 ACR criteria for FM lacked important illness features such as fatigue, morning stiffness, disturbed sleep, affective distress, etc. Wolfe et al remedied this omission by including several of these features, such as nonrestorative sleep, fatigue, and dyscognition, into the new criteria. Nevertheless, there is a glaring omission of well-known mechanistic FM features, such as hyperalgesia, central sensitization, or dysfunctional pain modulation.

We also doubt that the new criteria can provide more precision (specifically for characterization of FM subgroups) mostly because of the vagueness of the proposed criteria (fatigue, dyscognition, and nonrestorative sleep). Also, the somatic symptom list is extremely broad (41 somatic symptoms), and the symptoms are ordered by neither relevance nor predictive value, etc., supposedly contributing equally to FM. In conclusion, whether or not these new criteria are easy to apply by practicing physicians will require empirical testing. Unfortunately, the new criteria are imprecise, ill-defined, lack mechanistic features, and are completely symptom focused. They also subscribe to the same circular logic as the 1990 ACR criteria. Would it be better to teach physicians how to test tender points and therefore keep the old criteria? New criteria for FM are needed, but we doubt that Wolfe and colleagues have made the necessary quantum leap to advance this important issue.

Dr. Staud has received consultant fees, speaking fees, and/or honoraria (less than $10,000 each) from Forest Laboratories and Jazz Pharmaceuticals.

R. Staud, MD
D. D. Price, PhD
M. E. Robinson, PhD
University of Florida
Gainesville, FL

DOI 10.1002/acr.20291

Reply

To the Editors:

We thank Drs. Thompson, Vanderschueren, Staud, and colleagues for their comments on the new diagnostic criteria for fibromyalgia. We note that Dr. Thompson finds the ACR 2010 criteria problematic because she feels there can be confusion between fibromyalgia and MPS, when the latter affects several body regions. It seems unavoidable that disorders that affect muscle might cause confusion with fibromyalgia. However, as noted by Dr. Thompson, in the case of MPS there are criteria that exist to define MPS. So ordinarily the 2 disorders should be distinguishable except, of course, if they are both present simultaneously. We hope that clinicians who use diagnoses like fibromyalgia and MPS would apply current diagnostic methods at the time of diagnosis.

We are grateful to Dr. Steven Vanderschueren and colleagues for raising very important questions about our study and criteria. To paraphrase their first point, they indicate that pain is not simple and that criteria that abandon the physical examination may result in poor medical care. We address this point in our criteria article when we state, "Even though the new criteria do not include a physical examination criterion, all of the patients being diagnosed should have a physical examination, which may include examination of tender point sites. . .It is important for physicians to perform an appropriate clinical assessment to exclude other diagnoses, and/or to identify potential coexisting rheumatic diseases that may require treatment themselves." For clinical assessment, we would include some measure of tenderness or pain threshold, but not necessarily a formal tender point count.

Where Vanderschueren et al indicate that "the article clearly shows that the tender point count is the most reliable feature to differentiate fibromyalgia and nonfibromyalgia patients," we would respond that it is true, of course, because we used the 1990 criteria (1) as a gold standard. That does not mean that tender points are better than other methods; it merely means that they represented the gold standard test for the criteria development. There are substantial issues with the reliability of the tender point examination.

In their second point, Vanderschueren et al state, "The new diagnostic criteria, as opposed to the ACR 1990 classification criteria, implicitly state that fibromyalgia should

be a diagnosis of exclusion, without detailing what painful disorders should be ruled out or what tests should be performed for that reason. In contrast, the 1990 classification criteria made no exclusions for the presence of concomitant radiographic or laboratory abnormalities and abandoned the distinction between primary fibromyalgia and secondary-concomitant fibromyalgia." We think that Vanderschueren and colleagues have misinterpreted our discussion of exclusionary diagnoses. As a study exclusion criterion, we wrote, "The patient does not have a disorder that would otherwise explain the pain," and we indicated that "implicit in the 1990 ACR classification criteria was the requirement that clinical examination and clinical judgment had excluded other causes of chronic widespread pain, and such an exclusion is also implicit in the proposed diagnostic criteria." Most of us, for example, would not exclude other rheumatic diseases.

Vanderschueren and colleagues make their third point by saying, "The control group consisted of patients with noninflammatory painful rheumatic disorders. The proportion of control persons with a fibromyalgia diagnosis increased >4-fold (from 2.0% using the 1990 criteria to 9.1% using the new criteria)." We believe this is not correct. The false-positive rate in the 1990 criteria was 18.9% (1). In this third point Vanderschueren and colleagues also wonder whether abandoning the tender point count will open "Pandora's Box." If we understand Vanderschueren et al correctly, they are worried about misdiagnosis, i.e., calling other conditions fibromyalgia that are really not fibromyalgia. This question really goes to the heart of what fibromyalgia means in the presence of other illnesses. Perhaps some of the patients Vanderschueren and colleagues are worried about should be classified as fibromyalgia patients. We would also point out the strong correlation between the WPI and the tender point count, as shown in Table 3 of the 2010 criteria, and the similar association of both variables with the symptoms we are concerned with. Based on the data from our study, we think it is very unlikely that the new criteria will misclassify many patients.

The fourth point made by Vanderschueren and colleagues is that fibromyalgia patients in this study were older (mean age 54.6 years), suggesting that many had the label for quite some time. In a recent population study, the mean age of fibromyalgia patients was 48.9 years (2). If age is a random variable, we expect age to vary from sample to sample. Even so, age made no difference in the results of our study. In response to the point made by Vanderschueren and colleagues that "a fair share of subjects ended up in the 'prior fibromyalgia' category," we would have to observe that "prior" doesn't reflect age, but rather reflects diagnostic change.

In their fifth point, Vanderschueren et al are concerned that "many patients (36.4%) entering the present study as fibromyalgia patients were labeled as such not based on the ACR classification criteria, but on the personal judgment of the study physician." The choice to allow patients who were diagnosed without ACR criteria was deliberate. In attempting to slightly change the case definition of fibromyalgia, we wanted to know how rheumatology physicians were defining the disorder. That is, what is the current actual case definition in practice? It has been known from the time of the 1990 criteria that experts might make a diagnosis even when criteria were not satisfied. Vanderschueren et al confuse patients used to make a more valid case definition and the actual criteria that were evaluated against the 1990 criteria. Fibromyalgia can be a difficult problem. We believe that we have scientifically addressed the case definition and found the best criteria for the condition.

If we understand what seems to be Dr. Staud's main point correctly, that we omitted "well-known mechanistic FM features, such as hyperalgesia, central sensitization, or dysfunctional pain modulation" from the criteria, we would reply that central sensitization and dysfunctional pain modulation are not features that can be reasonably assessed in the clinic, and that the widespread pain index provides a measure of hyperalgesia that, as the data show, is equivalent to the tender point count.

With respect to the symptom list, Dr. Staud is mistaken about not reporting the predictive value of the symptoms. We do report the importance of the symptoms in Figure 2, and in importance order. Dr. Staud may assume that variables not in the figure do not contribute to classification.

Dr. Staud writes that we "promote new diagnostic criteria that are almost as good (80% correct classification) as the previous criteria." This is not correct. Table 5 shows that among patients satisfying ACR 1990 criteria, 88.1% satisfied 2010 criteria in phase 1 and 95.2% in phase 2. In addition, when all patients are considered, not just ACR 1990 positive patients, we wrote in the text, "It should be remembered that physician diagnosis only correctly classified 84.1% of cases, while the proposed diagnostic criteria, even with shift of definition, identified 82.6% of patients correctly."

Dr. Staud writes, "They [the criteria] also subscribe to the same circular logic as the 1990 ACR criteria." He should reread the paragraph in the discussion beginning with, "Readers might wonder: why is it so difficult to make new fibromyalgia criteria? The central problem in fibromyalgia criteria is the absence of a gold standard or case definition." Later in the paragraph we point out that, "In the current study, we derived an empirical case definition from the variable importance analyses."

If Dr. Staud is not satisfied with the new criteria, he may continue to use the old ones (the ones he criticized for being circular). But one advantage to the new criteria that warrants mentioning is that the change in the case definition demands that the patient's symptoms be paid attention to. Who would want less?

Frederick Wolfe, MD
National Data Bank for Rheumatic Diseases and University of Kansas School of Medicine
Wichita, KS
Daniel J. Clauw, MD
University of Michigan Medical School
Ann Arbor, MI
Mary-Ann Fitzcharles, MB, ChB
Montreal General Hospital and McGill University

Montreal, Quebec, Canada
Don L. Goldenberg, MD
Newton-Wellesley Hospital and Tufts University School of Medicine
Boston, MA
Winfried Häuser, MD
Technische Universität München
Munich, Germany
Robert S. Katz, MD
Rush University Medical Center
Chicago, IL
Philip Mease, MD
Seattle Rheumatology Associates and Swedish Medical Center
Seattle, WA
Anthony S. Russell, MD
University of Alberta
Edmonton, Alberta, Canada
I. Jon Russell, MD, PhD
University of Texas Health Sciences Center
San Antonio, TX
John B. Winfield, MD
University of North Carolina
Chapel Hill, NC

1. Wolfe F, Smythe HA, Yunus MB, Bennett RM, Bombardier C, Goldenberg DL, et al. The American College of Rheumatology 1990 criteria for the classification of fibromyalgia: report of the Multicenter Criteria Committee. Arthritis Rheum 1990;33:160–72.
2. Hauser W, Schmutzer G, Brahler E, Glaesmer H. A cluster within the continuum of biopsychosocial distress can be labeled "fibromyalgia syndrome": evidence from a representative German population survey. J Rheumatol 2009;36:2806–12.