A Comparative Evaluation of the 2011 and 2016 Criteria for Fibromyalgia

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ABSTRACT. ***Objective.*** In 2016, a revised version of the 2010 American College of Rheumatology fibromyalgia (FM) criteria and the 2011 self-report (survey) FM criteria were published. The 2016 criteria preserved the distinction between physician and patient criteria, but made the individual criteria items identical, added a "generalized pain" criterion, and changed ascertainment and scoring methods, among other changes. In this study, we evaluated diagnostic differences relating to 2016 changes.

Methods. We used the National Data Bank for Rheumatic Diseases and evaluated 16,987 participants with painful rheumatic disorders using the 2011 and 2016 methodologies.

Results. There were 4731 patients (27.9%) who satisfied the 2011 criteria and 4077 (24.0%) the 2016 revision. This resulted in agreement in 96.2% of cases and disagreement in 3.9%. All disagreements occurred in the 4731 2011-positive cases who failed to meet the 2016 criteria. This result came about because 654 (13.8%) of the 2011-positive cases failed to meet the new generalized pain requirement. When using the approximate polysymptomatic distress diagnostic method, diagnostic misclassification ranged between 7% and 13%.

Conclusion. The 2016 FM criteria further refined and increased the usefulness of symptom-based diagnosis of FM by excluding patients with regional pain syndromes. However, these changes, useful as they are, underscore the social construction of symptom-based diagnosis and the inherent limitations in reliability and validity associated with FM criteria. (J Rheumatol First Release June 1 2017; doi:10.3899/jrheum.170095)

Key Indexing Terms:
FIBROMYALGIA EPIDEMIOLOGY PAIN

Because there is no gold standard for the diagnosis of fibromyalgia (FM), diagnostic and classification criteria have been based on expert opinion consensus regarding what FM is.

Criteria for FM have evolved from a primarily tender point determination, as in the American College of Rheumatology (ACR) 1990 criteria[1], to one based on symptoms, although it is likely that underlying symptoms were always the driving force in FM diagnosis[2]. In 2010, the ACR preliminary diagnostic criteria for FM were published, which changed the characteristic of FM criteria[3]. The 2010 criteria were symptom severity criteria, based on accumulating and documenting sufficient pain and somatic symptoms as determined by a physician. One limitation to the 2010 criteria was that a physician was required to elicit symptoms and evaluate them, thereby limiting criteria usefulness in many research settings. In 2011, the 2010 authors promulgated a self-report version of the 2010 criteria for use in research[4]. These 2011 criteria differed only slightly from the 2010 criteria, but were designed for use in research, not in individual patient diagnosis.

In 2016, a systematic review of 2010/2011 criteria studies concluded that there were high levels of agreement in sensitivity and specificity between the ACR 1990 criteria and the newer 2010/2011 criteria[2]. Even so, problems with the 2010/2011 criteria were identified, including imprecise language and definition, lack of clarity regarding FM diagnosis in the presence of other diseases[5], differing assessments for the 2010 and 2011 criteria, inability to exclude some regional pain syndromes[6], and inherent limitations to validity and reliability[7]. Based on these observations, the 2016 committee (composed primarily of 2010 and 2011 members) promulgated the 2016 revisions to address these issues[2]. The 2016 criteria preserved the distinction between physician and patient criteria but made the individual criteria items the same for each method, and added a "generalized pain" criterion to avoid inappropriately including regional pain syndromes in the FM definition. Atypical chronic limb pain syndromes, chronic temporomandibular joint disorder, and chronic pelvic pain syndrome are examples of such regional pain syndromes, which may be accompanied by significant somatic symptoms sufficient to establish a diagnosis of FM based on the 2010/2011 criteria. Patients having such a clinical constellation of symptoms may in fact

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Accepted for publication March 31, 2017.

have a functional disorder that has a clinical and possibly a pathogenetic overlap with FM. Moreover, it is reasonable to assume that such patients with chronic pain may benefit from the implementation of therapeutic options used in FM such as cognitive behavioral treatment and alternative treatments. Nonetheless, these patients would not usually be considered to represent patients with FM because they lack the basic prerequisite of chronic pain.

In addition, the 2016 criteria made explicit how pain sites should be evaluated and scored, restored the 1990 criterion that FM was a valid diagnosis regardless of concomitant disease, strongly suggested the use of the polysymptomatic distress scale (PSD), and noted potential problems in FM diagnosis. The 2016 criteria are meant to replace the 2010 and 2011 criteria.

In our current report, we applied the 2011 and 2016 criteria to a large dataset of patients with rheumatic disease to see the effect of 2016 changes on FM diagnosis, including the approximate diagnosis available using the PSD.

MATERIALS AND METHODS

We used the longitudinal research database of the National Data Bank for Rheumatic Diseases (NDB) to evaluate the 2016 criteria. The details of the NDB and its activities have been reported previously[8,9]. Beginning in 2010, the NDB collected FM criteria items from all participants completing its semiannual research questionnaire. From each of the 16,987 participants, we randomly selected a single observation for further study. As previously reported, the NDB primarily collects data from patients with rheumatic diseases[8]. In our study, we reported on 12,037 with rheumatoid arthritis, 2359 with a noninflammatory rheumatic disorder, 1602 referred with a diagnosis of FM, and 989 with systemic lupus erythematosus.

Ethical approval. The study was approved by the Via Christi institutional review board, Wichita, Kansas, USA (FWA00001005).

The Widespread Pain Index (WPI; 0–19). The WPI is a summary count of the number of 19 painful regions from the regional pain scale, a self-reported list of painful regions[10]. Regions include:

1. Left upper region (region 1): left jaw, left shoulder girdle, left upper arm, left lower arm.
2. Right upper region (region 2): right jaw, right shoulder girdle, right upper arm, right lower arm.
3. Left lower region (region 3): right hip (buttock, trochanter), right upper leg, right lower leg.
4. Right lower region (region 4): hip (buttock, trochanter), right upper leg, right lower leg.
5. Axial region (region 5): neck, upper back, lower back, chest, abdomen.

The Symptom Severity Scale (SSS; 0–12). The SSS is the sum of the severity scores of 3 symptoms (fatigue, waking unrefreshed, and cognitive symptoms; 0–9) plus the sum (0–3) of the number of the following symptoms the patient has been bothered by that occurred during the previous 6 months: (1) headaches (0–1), (2) pain or cramps in lower abdomen (0–1), and (3) depression (0–1).

Details of the PSD (0–31). The PSD, also known as the FM severity score, is the sum of the WPI and SSS. The PSD scale measures the magnitude and severity of FM symptoms in those satisfying and not satisfying criteria.

Widespread pain (WP). The WP criterion was first described in the 1990 FM criteria[1]: "Pain is considered widespread when all of the following are present: pain in the left side of the body, pain in the right side of the body, pain above the waist, and pain below the waist. In addition, axial skeletal pain (cervical spine or anterior chest or thoracic spine or low back) must be present. In this definition, shoulder and buttock pain is considered as pain for each involved side. "Low back" pain is considered lower segment pain[1]. As noted elsewhere, "The 1990 definition, however, is inexact because it does not state which body areas should be included in the body pain assessment. In addition, rare patients who otherwise met the 1990 criteria could satisfy the ACR WP definition with pain in only a few areas. For example, in the presence of axial pain, low back pain, and pain in the right hand and left foot would qualify as WP. This occurs because pain in a single site can be expanded to include more than 1 region, as when right hand pain is scored for right side and for upper extremity.[11]"

Generalized pain. Pain in at least 4 of 5 regions described above must be present. Jaw, chest, and abdominal pain are not included in the generalized pain definition[2].

ACR 2010 criteria. "A patient satisfies modified ACR 2010 FM diagnostic criteria if the following 3 conditions are met: (1) WPI ≥ 7 and SSS ≥ 5 or WPI between 3–6 and SSS > 9. (2) Symptoms have been present at a similar level for at least 3 months. (3) The patient does not have a disorder that would otherwise sufficiently explain the pain.[4]" The 2011 criteria are almost the same, but apply only to self-reported data.

ACR 2016 criteria. A patient satisfies modified 2016 FM criteria if the following 3 conditions are met: (1) WPI ≥ 7 and SSS score ≥ 5 OR WPI of 4–6 and SSS score ≥ 9. (2) Generalized pain, defined as pain in at least 4 of 5 regions, must be present. Jaw, chest, and abdominal pain are not included in generalized pain definition. (3) Symptoms have been generally present for at least 3 months. (4) A diagnosis of FM is valid irrespective of other diagnoses. A diagnosis of FM does not exclude the presence of other clinically important illnesses.[2]

Other study variables. In addition, patients completed visual analog scales that were scored as 0–10. The scale questions and anchors were (1) severity of pain over the last week, with anchors from no pain to severe pain; (2) global severity: "…all of the ways your illness affects you … rate how you are doing," with anchors of very well and very poor. Patients reported functional status using the Health Assessment Questionnaire[12].

Statistical analyses. Analyses were performed using Stata 14[13]. We calculated the "best" cutpoint (empirical optimal cutpoint) for PSD to identify the 2011 and 2016 FM criteria positivity using the Liu method[14]. Sensitivity and specificity of the 2011 and 2016 criteria were described using Stata's roctab procedure[13].

RESULTS

Of the 16,987 persons evaluated, 4731 (27.9%) satisfied the 2011 criteria and 4077 (24.0%) the 2016 revision. This resulted in agreement in 96.2% of cases and disagreement in 3.9%. All disagreements occurred in the 4731 2011-positive cases who failed to meet the 2016 criteria. This result came about because 654 (13.8%) of the 2011-positive cases failed to meet the new generalized pain requirement of 4 pain regions and in effect, a WPI minimum score of 4 rather than the minimum of 3 called for in the 2011 criteria. No other variable contributed to the difference between 2016 and 2011 definitions once generalized pain was considered. As shown in Table 1, those in whom 2011 and 2016 criteria differed had similar SSS values, but lower WPI and PSD. As expected, their region count was also lower (4.8 vs 2.8), as were the left and right pain locations percentages. Thus, those who previously qualified for the FM definition but now did not had fewer pain symptoms. In addition, in this FM group not qualifying under the 2016 definition, 34 (0.7%) had 1 positive pain region, 87 (1.8%) had 2 regions, and 533 (11.3%) had 3 regions. The location of these patients

Table 1. Comparison of patients who are 2011 criteria–positive and 2016 criteria–positive with those who are 2011 criteria–positive and 2016 criteria–negative. All comparisons are significant at $p < 0.05$.

Variable	Criteria Agreement, 2011+ and 2016+, n = 4077	Criteria Disagreement, 2011+ and 2016–, n = 654
PSD	21.1	14.9
SSS	7.8	8.1
WPI	13.3	6.7
Generalized pain, %	100.0	0.0
Widespread pain, %	99.0	59.3
Region count	4.8	2.8
Region count of 5, %	84.3	0.0
Axial pain, %	98.8	96.1
Left upper pain, %	95.4	44.8
Right upper pain, %	96.7	48.3
Left lower pain, %	96.1	43.9
Right lower pain, %	97.4	43.1
Age, yrs	56.0	54.6
VAS pain, 0–10	6.4	5.6
HAQ, 0–3	1.5	1.3
VAS patient's global, 0–10	6.0	5.4

PSD: polysymptomatic distress scale; SSS: Symptom Severity Scale; WPI: Widespread Pain Index; VAS: visual analog scale; HAQ: Health Assessment Questionnaire Functional Disability Scale.

on the PSD histogram is shown graphically in Figure 1. Those patients for whom a discrepancy was observed between the 2011 and 2016 criteria (i.e., 2011 criteria–positive and 2016 criteria–negative) were centered in the PSD range between 12 and 24.

In the clinic and in previous studies, patients have sometimes been characterized as having or not having FM based on the level of their PSD. Using this method, there is loss of classification accuracy, but this has not been carefully quantified previously. The 2011 criteria use the PSD variables (WPI and SSS) for diagnosis, but the 2016 criteria additionally apply the generalized pain criterion — a factor that reduces the accuracy of prediction by PSD minimally. As shown in Table 2, the sensitivity, specificity, and receiver-operation characteristic score for 2016 diagnosis were 0.94, 0.91, and 0.93, respectively, compared with 0.97, 0.91, and 0.94 for the 2011 criteria. There was no actual best cutpoint; the best cutpoint depended on whether one wanted to maximize sensitivity, specificity, or some measure of both sensitivity and specificity. For both sets of criteria, a PSD value ≥ 12 was 100% sensitive. Depending on the cutpoint chosen in this dataset, diagnostic misclassification of the approximate PSD-based diagnosis was between 7% and 13%.

The original WP definition, as in the ACR 1990 FM criteria, was much easier to satisfy than the 2016 generalized pain criterion. As shown in Table 1, among those 2011-positive patients who did not satisfy 2016 criteria, 59.3% satisfied the 1990 WP criterion. This is also shown in Figure 2, where the percent of persons positive for an FM diagnosis was always greater when widespread pain rather than generalized pain was a requirement.

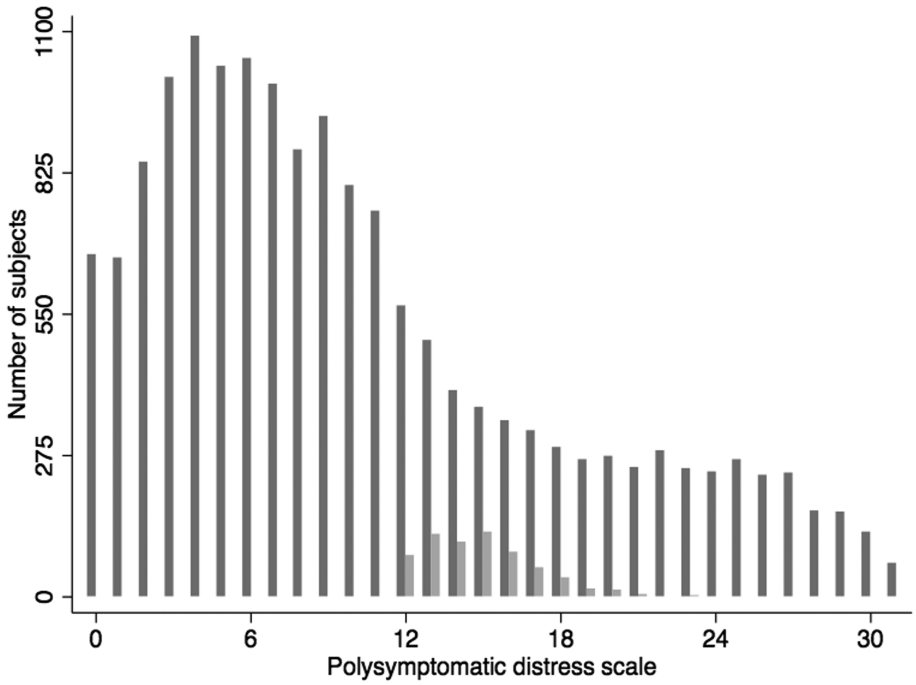

Figure 1. Location on the polysymptomatic distress scale of patients who were 2011- and 2016-positive (dark grey lines) and those 2011-positive and 2016-negative (light grey lines).

Table 2. Sensitivity, specificity, and cutpoint for the 2011 and 2016 criteria based on PSD scores. Actual cutpoint is next whole number above EOC. An EOC of 13 is actualized as ≥ 14.

Criteria	Cutpoint	Sensitivity, %	Specificity, %	Correctly Classified, %
2016 Criteria: EOC 13, sensitivity 0.94, specificity 0.91, ROC 0.93	≥ 12	100.00	82.92	87.02
	≥ 13	97.99	87.30	89.87
	≥ 14	94.26	90.93	91.73
	≥ 15	88.99	93.20	92.19
	≥ 16	82.12	94.86	91.80
	≥ 17	75.10	95.96	90.95
	≥ 18	68.43	96.80	89.99
2011 Criteria: EOC 12, sensitivity 0.97, specificity 0.91, ROC 0.94	≥ 12	100.00	87.34	90.87
	≥ 13	96.55	91.30	92.77
	≥ 14	90.76	94.13	93.19
	≥ 15	83.98	95.65	92.40
	≥ 16	75.40	96.37	90.53
	≥ 17	67.53	96.83	88.67
	≥ 18	60.58	97.25	87.04

PSD: polysymptomatic distress scale; EOC: empirical optimal cutpoint; ROC: receiver-operation characteristic.

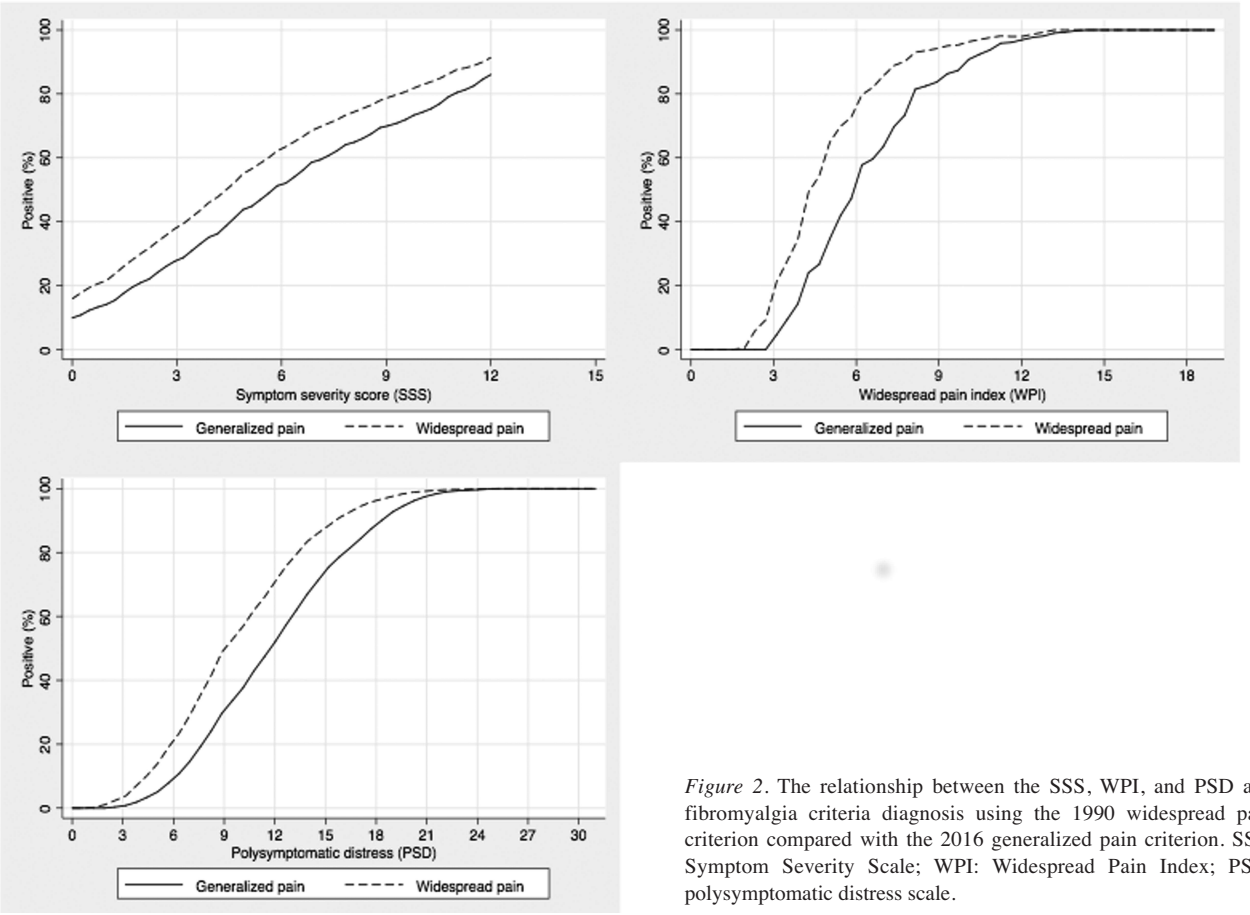

Figure 2. The relationship between the SSS, WPI, and PSD and fibromyalgia criteria diagnosis using the 1990 widespread pain criterion compared with the 2016 generalized pain criterion. SSS: Symptom Severity Scale; WPI: Widespread Pain Index; PSD: polysymptomatic distress scale.

DISCUSSION

The data of our study show in a large mixed sample of patients with rheumatic disease with pain that the new 2016-revised criteria do not misclassify positive patients who were negative in the 2011 criteria. All the change in criteria status occurred in those who were positive by the 2011 criteria, amounting to 13.8% of all 2011-positive subjects and 3.9% of all patients. This change in status is the result of the new requirement to have 4 of 5 regions positive, a status that has been labeled as generalized pain. The 2016 requirement was imposed to prevent persons with severe regional pain syndromes from satisfying FM criteria. As noted, while some overlap may exist between these patients having chronic regional pain as part of a functional disorder and patients with FM, these patients, who may be more common in particular settings such as tertiary pain clinics, do not comply with the common consensus of what FM represents.

We also found that the 2016 generalized pain criterion was "stricter" than the 1990 widespread pain criterion even though the 2016 definition allowed persons who did not meet the 4-quadrant and axial pain requirement of 1990 widespread pain. This occurred because the 1990 criterion allowed painful sites to contribute pain to more than 1 region at the same time. Generalized pain appears to be a much better (more discriminating) criterion, being defined as at least 4 painful separate and nonoverlapping regions. Among those meeting the 2016 criteria, 84.3% had 5 painful regions and 15.7% had 4 painful regions.

We reported previously that there is good agreement between patients satisfying the 1990 and the 2011 criteria[2]. The 2016 revision ensures that patients with regional pain syndromes will not be misclassified as having FM. The price for this assurance is to regard almost 14% of patients previously diagnosed, perhaps incorrectly, by the 2011 criteria as having FM as not having FM by the 2016 criteria, and raises once again the issue of criteria, diagnosis, and the characteristic of FM.

The design of the FM criteria. There is no gold standard that defines FM and against which FM criteria may be compared. Beginning in the 1970s, each succeeding set of criteria has identified slightly or substantially different sets of patients. Almost all criteria sets have been based on identifying patients who fit current expert and nonexpert ideas of what FM is. However, studies in the 2012 US National Health Interview Survey (NHIS) indicate that most patients who received a diagnosis of FM from a health professional would not satisfy published FM criteria. Criteria notwithstanding, 1 recent characterization from a major FM research center described FM as "the current term for chronic widespread musculoskeletal pain for which no alternative cause can be identified,"[15] an idea at variance with all previous definitions. Published experiences on the Internet from patients indicate that a diagnosis of FM often depends on which physician evaluates the patient. Some physicians are considered skilled, others unskilled, still others unbelieving. Criteria involve subjective assessments and interpretations, and are influenced by social contexts. In addition, it is now recognized that FM symptoms and findings are measured with error that is often sufficient to question criteria accuracy when diagnosis depends on crossing a symptom severity (WPI and SSS) border[2,7].

FM diagnosis and criteria also falter in the situation where a patient who once met FM criteria now fails to meet criteria. Clinical problems also arise when a patient "almost" meets criteria, missing just slightly, and FM can also overlap with entities such as chronic fatigue syndrome, leading to contentions as to whether the disorders are the same disorder or should be treated as comorbid conditions.

Properly applied, criteria provide a framework for a contemporary definition of FM. The 2010, 2011, and 2016 criteria revisions characterize FM as a mixture of widely distributed body pain and distressing non-pain symptoms. Both pain and non-pain symptoms must be present at sufficient levels of severity. The PSD (also called the FM severity scale) combines the symptoms and pain to provide a continuous measurement of overall symptom severity that aids in understanding FM and FM diagnosis. Figure 1 and Figure 2 demonstrate how increases in the PSD level increase the likelihood of FM diagnosis, while setting the baseline requirement that PSD reaches a minimum level of 12. This minimum PSD value is also applicable for epidemiological survey purposes. Choosing a different PSD minimum value in the current criteria would obviously cause difficulty on comparing current and previous epidemiological studies, based on the previous sets of criteria. Physicians, regulators, and authorities who use the current criteria or the PSD alternative for diagnosis or understanding should encounter a representative and useful definition of the disorder. Recognizing the PSD and incorporating it into medical education is important for rheumatologists as well as for other physicians dealing with musculoskeletal pain, because this tool can be useful in the evaluation and management of many patients carrying a broad range of diagnoses and can be vital in properly assessing response to treatment.

Although the criteria provide a useful definition, there are substantial limitations, as indicated above. FM and FM criteria are inherently subjective, culture- and context-driven, and subject to measurement error. There are substantial and continuing problems relating to definition, validity, and reliability. Criteria should be used in teaching about FM and as an aid in diagnosis in the clinic. Criteria are mandatory in any research study and must be contemporary, not historical, because FM is defined by current symptom status.

Because FM diagnosis occurs in a social setting, there are several situations in which a diagnosis may be desirable to one of the parties and in which validity of criteria-based diagnosis can be tenuous. For physicians, a diagnosis of FM may offer an explanation of difficult-to-understand symp-

toms, as was probably the case of many misclassified patients in the NHIS[16,17]. For patients, a diagnosis of FM can offer confirmation that symptoms are real, not psychological. In the United States, the US Social Security Administration (SSA) requires that the disabling diagnosis must be "medically determined"[18]. Because FM symptoms are self-reported, diagnosis for insurance, SSA, and other disability assessment purposes will always be limited in validity and reliability.

The use of a PSD in patients with FM-like symptoms obviates some of these problems because it acknowledges and quantifies FM-like symptoms without disregarding individual characteristics. The 2016 criteria committee suggested that the PSD always be used when the criteria are invoked.

The 2016 FM criteria further refine and increase the usefulness of symptom-based diagnosis of FM by excluding patients with regional pain syndromes. However, these changes, useful as they are, underscore the social construction of symptom-based diagnosis and the inherent limitations in reliability and validity.

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