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Estimates of Responsiveness, Minimally Important Differences, and Patient Acceptable Symptom State in Five Patient-Reported Outcomes Measurement Information System Short Forms in Systemic Lupus Erythematosus

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Objective. Examinations of Patient-Reported Outcomes Measurement Information System (PROMIS) measures in adult systemic lupus erythematosus (SLE) have provided support for their cross-sectional validity in SLE. We estimated responsiveness to change, meaningful changes (minimally important differences [MIDs]), and the patient acceptable symptom state (PASS) for five PROMIS short forms to facilitate longitudinal use and interpretation of PROMIS scales in SLE.

Methods. Data from five administrations of PROMIS short forms in the FORWARD SLE cohorts were used. Pearson correlation coefficients were used to assess associations between changes in PROMIS measures and changes in anchor measures for responsiveness analyses. Worse, same, or better groups were defined for each anchor. Differences in PROMIS scores were calculated for each consecutive PROMIS administration; mean changes in PROMIS scores of individuals in the worse, same, and better groups were calculated. Both anchor-based and distribution-based methods were used to estimate MIDs. PASS was defined as the 75th-percentile positive score among those who considered their health to be acceptable or who were somewhat or very satisfied with their health.

Results. All PROMIS short forms showed adequate responsiveness to changes in related patient-reported outcomes. However, only the fatigue and pain interference scales were responsive to self-reported SLE activity. Taking into account all methods, we estimated MIDs for each scale to be approximately two points. All PASS values were better than the population mean T-score of 50.

Conclusion. These results support use and further study of PROMIS short forms in SLE and should facilitate interpretation of PROMIS scores and changes.

INTRODUCTION

Clinical care and research in rheumatic diseases rely heavily on patient-reported measures to assess disease activity, progression, and treatment effectiveness. The National Institutes of Health's (NIH's) Patient-Reported Outcomes Measurement Information System (PROMIS) measures represent the most comprehensive suite of patient-reported outcome (PRO) measures available. PROMIS measures include domains commonly measured for systemic lupus erythematosus (SLE) studies (eg, pain, fatigue, and physical functioning) as well as domains that are relevant and important to patients with SLE (eg, social functioning and sleep) but are not often measured (1,2). The first examinations of PROMIS in adult SLE cohorts have provided support for the cross-sectional validity of both the short-form and computer-adaptive test versions of several of the measures in SLE (3–8). What is lacking to support full implementation of PROMIS in studies of SLE are examinations of its longitudinal performance to determine responsiveness to changes in health or disease status and to identify meaningful changes to aid in interpretation of scores.

Responsiveness is considered an aspect of construct validity and is determined by evaluating the relationship between changes

in the PROs under study and changes in relevant clinical or other patient-based end points (9). Some studies have examined the responsiveness of PROMIS measures in other conditions (10–15), but information on the responsiveness of PROMIS measures to change in SLE does not exist. Likewise, a few studies have estimated meaningful changes (ie, minimally important differences [MIDs]), or the smallest change considered meaningful to patients (9), on PROMIS scales in osteoarthritis, rheumatoid arthritis, low back pain, and cancer (11,14,16–19), but no similar work has been done in SLE.

An additional factor that may aid in interpretation of scores is identification of the patient acceptable symptom state (PASS). The PASS is the highest symptom level at which patients consider themselves well (20). In simpler terms, improvement by MID measures "feeling better," whereas PASS measures "feeling good." No previous studies have identified PASS levels in PROMIS scores in SLE. These analyses examined a set of PROMIS short forms for responsiveness to change and to identify MIDs and PASS scores in SLE.

PATIENTS AND METHODS

Data sources: FORWARD (The National Databank for Rheumatic Diseases). Participants in FORWARD (21) are recruited primarily from rheumatologists, and diagnoses are provided by the rheumatologist. A minority of participants are enrolled from other sources, in which case diagnoses may be confirmed by participants' physicians or may be self-reported. In these analyses, only the participants with physician-confirmed SLE diagnoses are included. All other data are self-reported. Data were collected at six-month intervals. All participants had the option of completing the semiannual questionnaire online, as a mailed paper questionnaire, or by telephone interview. Among participants with SLE in the most recent questionnaire waves, approximately 60% responded online and 40% by mail questionnaire. All FORWARD procedures are approved by Via Christi Institutional Review Board, and all participants provide consent to participate.

Data shown in these analyses span five data collection periods during which the PROMIS short forms were included: July 2015 (T1; n = 239), January 2016 (T2; n = 299), July 2016 (T3; n = 292), January 2017 (T4; n = 274), and July 2017 (T5; n = 259). A recruitment effort was implemented between July 2015 and January 2016, increasing the sample size between those two administrations. Participants who did not complete consecutive questionnaires (n = 139) were not include in responsiveness or anchor-based MID analyses. A total of 481 individuals were included, with an average of 3.2 observations. Respondents had the option of completing questions at each administration, even if they had skipped a previous questionnaire. Most of the analyses here rely on changes from one questionnaire to the next. The option to skip questionnaires and the recruitment described above mean that there were variations in the number of individuals for whom changes could be calculated. The number of individuals in each change period were as follows: T1 to T2, n = 224; T2 to T3, n = 253; T3 to T4, n = 241; and T4 to T5, n = 238.

Measures. *Patient-Reported Outcomes Measurement Information System*. Five four-item PROMIS short forms were administered: physical function, fatigue, pain interference, sleep disturbance, and participation in social roles and activities. All PROMIS scales were scored and converted to T-scores that had a population mean of 50 and SD of 10 using PROMIS scoring documentation available at http://assessmentcenter.net. For all PROMIS scales, higher scores reflect "more" of the construct being measured, whether that construct could be construed as positive or negative. For example, higher scores on the physical function and participation in social roles scales reflect better functioning and so are considered to be "better" scores; higher scores on the fatigue, pain interference, and sleep disturbance scales are considered "worse."

Measures used as anchors in responsiveness analyses. Responsiveness analyses examined whether changes in PROMIS measures were associated with changes in other end points, referred to as "anchors," as expected. Measures of the same constructs (eg, ratings of fatigue or other measures of physical function) were selected as the primary anchors (Table 1), as the associations with changes in these measures would be expected to be the strongest. As a secondary anchor, we also tested self-reported SLE disease activity to determine whether PROMIS measures were sensitive to changes in this more general factor, which might be important to their use in future studies.

Patient acceptable symptom state. To estimate PASS, the following item, specified by the developers of the PASS, was asked: "If your health was to remain for the rest of your life as it has been during the last 48 hours, would this be acceptable or unacceptable to you? Yes or no?" (20,27). Although not part of standard methods to ascertain PASS, we also examined the following item: "How satisfied are you with your health now? Very satisfied, somewhat satisfied, neither satisfied nor dissatisfied, somewhat dissatisfied, or very dissatisfied?" (28).

Other variables. Participants self-reported demographic characteristics and other health and disease characteristics.

Analysis. *Responsiveness*. Pearson correlation coefficients were calculated to assess associations between changes in PROMIS measures and changes in the anchor measures described in Table 1. For each anchor measure, three groups were defined (worse, same, and better) using the change criteria shown in Table 1. Improvement and worsening on the anchor measures were defined by established MIDs if such information had been published. For anchors for which MIDs had not been established, a change of 0.5 SD was used to approximate the MID (Norman GR: 29).

Table 1. Anchor measures used in responsiveness analyses

	Description of Measure	Mean ± SD (Range) in T1 Administration	Definition of Improvement/ Worsening[a]
Primary Anchors for Each PROMIS Scale			
Physical function			
HAQ-II (38)	HAQ scores range from 0 to 3, with higher score indicating worse function	0.96 ± 0.68 (0-3)	±0.22
SF-36 physical function	Subscale of the SF-36 (40)	55.3 ± 29.8 (0-100)	±5
Fatigue			
Fatigue rating	"How much of a problem has fatigue or tiredness been for you in the past week?" Rated as 0 (no problem) to 10 (major problem) in increments of 0.5	4.8 ± 3.0 (0-10)	±1.5 (0.5 SD)
SF-36 vitality	Subscale of the SF-36 (40)	39.5 ± 24.5 (0-90)	±5
Pain interference			
Pain rating	"How much pain have you had in the past week?" Rated as 0 (no pain) to 10 (severe pain)	4.0 ± 2.9 (0-10)	±1.5
SF-36 bodily pain	Subscale of the SF-36 (40)	51.3 ± 24.2 (0-100)	±5
Participation in social roles			
SF-36 social function	Subscale of the SF-36 (40)	64.9 ± 28.1 (0-100)	±5
Sleep impairment			
Sleep problem rating	"How much of a problem has sleep been for you in the past week?" Rated as 0 (no problem) to 10 (major problem)	4.7 ± 3.1 (0-10)	±1.5
Secondary Anchors, Examined for All PROMIS Scales			
SLE disease activity	"How active is your lupus today?" Rated as 0 (not active, in remission) to 10 (very active)	2.8 ± 2.7 (0-10)	±1.5 (0.5 SD)

Abbreviation: HAQ, Health Assessment Questionnaire; SF-36, 36-Item Short Form Health Survey; SLE, systemic lupus erythematosus; T1, time point 1.
[a]Minimally important differences have been published for an HAQ and the SF-36 subscales; these were used to define improvement/worsening. For the remaining scales, 0.5 AD of the T1 score, rounded to the nearest possible score (ie, increments of 0.5), was used to define improvement/ worsening.

Changes in individual anchor measure scores were calculated for each pair of time points (eg, change from T1 to T2); individuals could contribute up to four change scores. Assignments to worse, same, and better anchor groups were independent across change periods. Mean changes in PROMIS scores of individuals falling into the worse, same, and better anchor groups were calculated for each change period. Standardized response means (SRMs) (mean change/SD of change) and effect sizes (ESs) (mean change/SD of baseline) were calculated for the worse and better groups (10,30). Mean changes in PROMIS scores, SRMs, and ESs were then averaged over the four change periods. SRMs and ESs between 0.2 and 0.50 were considered small, SRMs and ESs between 0.50 and 0.80 were considered moderate, and SRMs and ESs greater than 0.80 were considered large. SRMs and ESs less than 0.20 were considered negligible and reflective of lack of responsiveness.

Minimally important differences. Both anchor-based and distribution-based methods were used to estimate MIDs, as recommended, to triangulate on a range of MID values (9). For the anchor-based analyses, the primary anchor used, which was available in questionnaires for all five administrations, was the following: "Compared to six months ago, would you say your health in general is: much better now, somewhat better now, about the same, somewhat worse, or much worse?" All questionnaires also included items asking for comparisons of pain and functioning to six months ago.

In a single time period, additional anchor questions were included, linked to the specific content of the PROMIS scales, and asked individuals to rate changes in pain interference with daily activities, fatigue, ability to do activities with friends and family, and sleep quality against six months ago. As with the responsiveness analyses, mean changes in PROMIS scores were calculated for each anchor response group. Individuals could contribute up to four PROMIS change scores. Mean changes in PROMIS scores of each anchor response group were then calculated.

For anchor-based analyses, the mean change of individuals responding "somewhat worse" was used as the estimate for the worsened MID; the mean change of individuals responding "somewhat better" was used as the estimate for the improvement MID (31).

Distribution-based estimates of MID were based simply on the distribution of observed scores, without attribution of an anchor. The standard error of measurement (SEM) has been recommended as one estimate of the MID (32). The SEM reflects the precision of measurement and can be interpreted as the smallest difference likely to reflect a true difference rather than measurement error. It is calculated as (S_o × square root [1 − r]), where S_o is the observed SD, and r is the reliability. Others have suggested that 0.5 SD and 0.35 SD are reasonable approximations of the MID (29,33,34). For distribution-based estimates, three estimates were calculated: (1) the SEM, (2) 0.5 SD, and (3) 0.35 SD.

Table 2. Characteristics of the FORWARD cohort (time 5, n = 290)[a]

Characteristics	Mean ± SD or % (n)	Range
Sociodemographic		
Age, y	61.2 ± 12.2	24–87
Female sex	94.0 (264)	…
White	82.4 (216)	…
≤ High school education	19.9 (52)	…
SLE-related		
Duration, y	25.0 ± 12.1	4–72
SLE disease activity rating	2.4 ± 2.5	0–10

Abbreviation: SLE, systemic lupus erythematosus.
[a]Includes only people with at least two observations. All variables are self-reported.

Patient acceptable symptom state. PASS was defined as the 75th-percentile positive score of those who consider their current state of health acceptable (27). The PROMIS pain interference, fatigue, and pain interference scales yield higher scores for more-negative health states. For these scales, the 25th-percentile score was used to maintain the original intent of the PASS method. An alternative estimation of PASS was defined the 75th-percentile score of those who were somewhat or very satisfied with their health. The former question was asked at a single time period. The latter was included in all questionnaires, so estimates from the five administrations were averaged.

RESULTS

Characteristics of the sample are shown in Table 2, and mean PROMIS scores for all administrations are shown in Table 3. For the PROMIS physical function, fatigue, pain interference, and sleep disturbance scales, mean scores were at least one-half SD worse than the population mean of 50.

Responsiveness. Table 4 presents the results of the responsiveness analyses and summarizes the data from the four change periods. Data from each individual change period are shown in Appendix Table 1, and the frequency distribution of responses in the anchor better, same, and worse categories is shown in Appendix Table 2.

Correlations between changes in all PROMIS scores and changes in primary anchor measures were generally small to moderate. For example, correlations of change in the PROMIS physical function scale with changes in the 36-Item Short Form Health Survey (SF-36) physical function subscale ranged from 0.32 to 0.46 in the four change periods. Changes in PROMIS scores, by and large, reflected changes in other measures. For example, changes in the PROMIS physical function scale for individuals who had meaningful improvements in the SF-36 improved by an average of 2.41 points; changes in the PROMIS physical function scale for those who had meaningful declines in the SF-36 decreased by an average of −2.63 points. SRMs and ESs were small to moderate.

Correlations between changes in the PROMIS physical function, participation in social roles, and sleep disturbance scores and changes in the secondary anchor of self-reported SLE disease activity were generally negligible (Table 4, Appendix Table 1), and responsiveness to disease activity was limited. In contrast, the PROMIS fatigue and pain interference scales did appear to be responsive to changes in self-reported SLE disease activity, although correlations and SRMs were small.

Minimally important differences. Distribution-based methods yielded similar estimates across scales (Table 5). The SEM includes estimates of scale internal consistency in the calculation (see MID analysis methods above). The internal consistency coefficients for these scales were all very high (0.95 or higher), yielding fairly small SEMs of approximately 2. The exception was the sleep disturbance scale, which had an internal consistency coefficient of 0.80 and an SEM of approximately 4. For all scales, the calculated SDs approximated the population SD of 10, yielding 0.5 SD of approximately 5 points, and 0.35 SD of approximately 3.5 points.

Anchor-based methods, however, yielded very different results, and in many cases, estimates of MID were very small (less than 1 point). Although MID estimates are based on score changes of those responding "somewhat better" and "somewhat worse," Table 6 provides the full distribution of responses to anchor items to show the pattern of changes over the full range of responses. Appendix Table 3 shows the number of respondents in each change category for each anchor item.

Table 3. PROMIS scale scores at each time point

	Time 1	Time 2	Time 3	Time 4	Time 5
N, total	285	340	333	290	290
n for responsiveness analyses[a]	—	224	253	241	238
Physical function, mean ± SD	42.4 ± 9.6	42.4 ± 9.6	42.0 ± 9.5	42.6 ± 9.6	42.9 ± 9.7
Fatigue, mean ± SD	56.4 ± 11.2	55.9 ± 11.5	56.1 ± 11.1	54.7 ± 11.8	54.7 ± 11.3
Pain interference, mean ± SD	56.8 ± 9.8	56.1 ± 9.8	57.3 ± 10.0	57.0 ± 9.7	56.7 ± 9.9
Sleep disturbance, mean ± SD	53.9 ± 9.2	53.2 ± 9.2	53.6 ± 9.6	52.9 ± 9.6	52.6 ± 9.7
Participation in social roles, mean ± SD	47.9 ± 10.1	48.6 ± 10.1	47.1 ± 9.8	47.7 ± 9.8	47.4 ± 10.4

Abbreviation: PROMIS, Patient-Reported Outcomes Measurement Information System.
[a]Number of individuals who completed two consecutive questions and for whom change scores could be calculated; for example, Time 2 n for responsiveness analysis = the number of participants who completed both the Time 1 and Time 2 questionnaires.

Table 4. Results of the responsiveness to change analysis

Anchor Criterion Measures for Each PROMIS Short Form	Correlation of Δ in Criterion Measure With Δ PROMIS[a]	Δ PROMIS[b]			Standardized Response Mean[b]		Effect Size[b]	
		Better[c]	Same[c]	Worse[c]	Better[c]	Worse[c]	Better[c]	Worse[c]
Physical function								
Primary								
HAQ-II	−0.31 to −0.42	2.52	−0.07	−2.66	0.43	−0.47	0.26	−0.28
SF-36 physical function	0.31 to 0.45	2.19	−0.28	−1.99	0.38	−0.37	0.23	−0.21
Secondary								
SLE disease activity	−0.01 to −0.21	0.86	−0.09	−0.92	0.16	−0.15	0.09	−0.10
Fatigue								
Primary								
0–10 fatigue rating	0.37 to 0.51	−4.14	−0.25	4.41	−0.60	0.62	−0.36	0.38
SF-36 vitality	−0.39 to −0.49	−3.01	−0.46	2.84	−0.43	0.43	−0.26	0.25
Secondary								
SLE disease activity	0.05 to 0.24	−1.75	−0.33	2.18	−0.24	0.29	−0.15	0.19
Pain interference								
Primary								
SF-36 pain (3)	−0.50 to −0.58	−4.00	0.19	3.89	−0.61	0.54	−0.41	0.40
0–10 pain rating	0.29 to 0.41	−2.64	−0.08	3.59	−0.37	0.46	−0.27	0.37
Secondary								
SLE disease activity	0.12 to 0.34	−2.23	0.04	2.79	−0.35	0.34	−0.23	0.28
Participation in social roles								
Primary								
SF-36 social function (3)	0.38 to 0.53	2.84	−0.12	−3.35	0.54	−0.48	0.29	−0.34
Secondary								
SLE disease activity	−0.07 to −0.21	1.27	−0.33	−1.33	0.19	−0.20	0.13	−0.13
Sleep disturbance								
Primary								
0–10 sleep rating	0.38 to 0.56	−3.97	−0.10	3.88	−0.56	0.65	−0.43	0.42
Secondary								
SLE disease activity	0.05 to 0.19	−1.21	−0.22	1.01	−0.19	0.15	−0.13	0.11

Abbreviation: HAQ-II, Health Assessment Questionnaire II; PROMIS, Patient-Reported Outcomes Measurement Information System; SF-36, 36-Item Short Form Health Survey; SLE, systemic lupus erythematosus.
[a]The range of correlation coefficients over the four change periods is shown.
[b]The means of changes in PROMIS scores, standardized means, and effect sizes over four change periods are shown. Data for individual time points are shown in Appendix Table 1.
[c]Better, same, and worse categories are defined by changes in the anchor criterion measure.

MID estimates were approximately 1 point for improvement and 2 points for worsening for the physical function scale, approximately 2 points for improvement and worsening for the fatigue scale, approximately 2 points for both improvement and worsening for the pain interference scale, less than 1 point for improvement and 1 to 2 points for worsening for the participation in social roles scale, and approximately two points for worsening and 1 to 2 points for improvement for the sleep disturbance scale.

Patient acceptable symptom state. In all cases, using the established question, PASS estimates were better than the PROMIS population mean T-score of 50, ranging from approximately 0.4 to 1.4 SDs (ie, 4-14 points) better (Table 6). Estimates derived from the satisfaction with health item were closer to the population mean.

DISCUSSION

The goals of these analyses were to evaluate the responsiveness of a set of PROMIS short forms and estimate values for MID and PASS in SLE to support their use in longitudinal analyses and

facilitate interpretation of changes in scores. Analyses of responsiveness showed considerable variation among PROMIS scales and among comparison measures within PROMIS scales. As would be expected, better responsiveness was noted for anchor scales more closely related to the PROMIS domain being evaluated (eg, for the PROMIS physical function scale, correlations with other measures of function were higher than correlations with SLE activity). In general, all PROMIS short forms for physical function, fatigue, pain interference, and participation in social roles showed adequate responsiveness to changes in other PROs.

Others have found moderate to high responsiveness of both the PROMIS physical function and pain interference short forms to changes in clinically measured disease activity in rheumatoid arthritis (12,18). In our analyses, however, only the fatigue and pain interference scales showed responsiveness to changes in self-reported SLE disease activity, suggesting that these domains play a more dominant role in patients' assessments of disease activity. In contrast, SRMs for the other PROMIS scales did not meet the minimum magnitude considered appropriate (0.3) (refs. 35 and 36). These other domains (physical function, participation

Table 5. Minimally important difference estimates in PROMIS short forms

PROMIS Short Form	Distribution Based[a]			Anchor Based: Mean Changes in PROMIS Score by Comparison Group[b]					
	SEM[c]	0.5 SD[c]	0.35 SD[c]	Comparison	Much Better	Somewhat Better	Same	Somewhat Worse	Much Worse
Physical function	2.35	4.80	3.36	Health[b]	3.74	0.79	0.09	−1.67	−3.18
	(2.34–2.37)	(4.77–4.83)	(3.35–3.38)	Function[b]	2.89	0.81	−0.06	−1.08	−3.34
Fatigue	1.97	5.69	3.98	Health[b]	−4.19	−1.87	−0.21	1.85	4.96
	(1.92–2.05)	(5.54–5.92)	(3.88–4.14)	Fatigue	−1.57	−2.28	0.05	1.91	6.34
Pain interference	2.20	4.92	3.44	Health[b]	−4.17	−1.38	−0.14	2.23	4.06
	(2.18–2.22)	(4.88–4.96)	(3.42–3.47)	Pain[b]	−2.72	−1.98	−0.16	1.91	4.93
Participation in social roles	2.00	5.01	3.51	Health[b]	2.54	1.28	0.25	−2.21	−6.06
	(1.95–2.08)	(4.89–5.21)	(3.42–3.64)	Social	−1.76	0.39	0.31	−2.16	−3.08
Sleep disturbance	4.23	4.73	3.31	Health[b]	−2.60	−1.98	−0.14	1.08	2.89
	(4.09–4.35)	(4.58–4.87)	(3.20–3.41)	Sleep	−6.40	−2.41	−0.50	2.53	3.16

Abbreviation: PROMIS, Patient-Reported Outcomes Measurement Information System; SEM, standard error of measurement.
[a]Distribution-based analyses: averaged over five administrations.
[b]Anchor-based analyses: These anchor measures were included in all questionnaire administrations. Changes in PROMIS measures were averaged over four change periods for these anchors. All other anchors were administered only once. In each case, respondents were asked to evaluate changes in the domain from 6 months ago.
[c]Mean (range); SEM was calculated as SEM = SD × the square root (1 − reliability).

in social roles, and sleep) may be viewed as less directly reflective of disease activity or may be affected by a broader or more complex array of factors. For example, physical function may be more closely linked to historical levels of physical activity or obesity in SLE; glucocorticoids, which may improve disease activity, may concurrently worsen sleep; and participation in social roles may be affected by depressive symptoms or even physical function.

MIDs estimated in these analyses are within the range of those suggested by analyses in other cohorts (Appendix Table 4). In general, MIDs recommended by other analyses in rheumatic or musculoskeletal conditions range from 2 to 3 points. For the physical function and satisfaction with social roles scales, we found slightly higher MIDs for worsening than for improvement, which may reflect a type of ceiling effect. With the exception of the sleep disturbance scale, the SEM (ie, smallest difference likely to reflect a true difference rather than measurement error) was also approximately 2 points, adding support to the estimate of 2 points as the MID.

PASS analyses have not previously been estimated for any of the PROMIS measures. Our analyses showed that to meet the PASS criterion, all PROMIS scores needed to be better than the

Table 6. PASS estimates

	Based on Established PASS Item ("Last 48 h")	Based on Satisfaction With Health Question[a]
Physical function	56.9	50.7
Fatigue	46.0	47.6
Pain interference	41.6	51.0
Satisfaction with social roles	64.2	55.4
Sleep disturbance	43.8	47.1

Abbreviation: PASS, patient acceptable symptom state.
[a]Averaged over five questionnaires.

population mean of 50 by 4 to 14 points. PASS estimates from the secondary method using satisfaction with health were generally closer to the population mean (± 4-6 points). Although results from this analysis can, therefore, provide a range of PASS values, additional work may be needed to refine these estimates. Results also provide evidence that using different questions to obtain PASS estimates can result in very different values.

These analyses were conducted in an observational setting, so it is possible that examinations of responsiveness, MIDs, and PASS in intervention studies, in which larger changes in disease status might be expected, may show different results. In fact, the majority of individuals in both groups had no change on the anchor measures (Appendix Table 2). However, there is evidence that some types of intervention studies may overestimate responsiveness because of inclusion criteria requiring specified (ie, high) levels of disease activity or flare and subsequent regression to mean health status (37). It is also possible that responsiveness, MID, and PASS estimates may vary according to initial levels of disease activity, disease duration, race/ethnicity, or language of administration. Unfortunately, we did not have sample sizes adequate to test these differences, so additional work is needed in this regard. Although we have previously found no systematic differences in PROMIS scores between individuals who completed questionnaires online compared with those who completed them on paper forms (Katz P: 3), it is possible that differences in the other scales may exist by mode of administration. It is also possible that individuals who take part in longitudinal observational studies, such as FORWARD, may be systematically different from those who do not, which may limit the generalizability of these findings.

Overall, we show that the physical function, fatigue, pain interference, and participation in social roles PROMIS short forms have moderate to good responsiveness to other PROs

measuring related constructs, but only the fatigue and pain interference scales were responsive to self-reported SLE disease activity. MIDs that are in the range of those identified in other studies of rheumatic and musculoskeletal conditions were identified. PASS estimates revealed that individuals aspire to health states equivalent to or better than those represented by the population average PROMIS scores. These results support use and further study of PROMIS short forms in SLE and should facilitate interpretation of PROMIS scores and changes.

AUTHOR CONTRIBUTIONS

All authors were involved in drafting the article or revising it critically for important intellectual content, and all authors approved the final version to be published, had full access to all of the data in the study, and take responsibility for the integrity of the data and the accuracy of the data analysis.

Study conception and design. Katz, Alemao, Yazdany, Dall'Era, Trupin, Michaud.
Acquisition of data. Pedro, Michaud.
Analysis and interpretation of data. Katz, Pedro, Alemao, Yazdany, Dall'Era, Trupin, Michuad.

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