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The impact of limited health literacy on patient-reported outcomes in systemic lupus erythematosus

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Abstract

Objective: Health disparities in patient-reported outcomes (PROs) by income and education are well documented; the impact of health literacy on PROs has received less attention. We examined independent effects of income, education, and health literacy on PROs in SLE.

Methods: Data from the California Lupus Epidemiology Study (CLUES, n=323) were used. Health literacy was assessed with a validated 3-item measure (ability to understand written information, reliance on others to understand written information, confidence in completing written forms). PROs were administered by interview in English, Spanish, Cantonese, or Mandarin. Generic and disease-specific PROs were examined: ten PROMIS short forms, the eight SF-36 subscales, and three patient-reported SLE disease activity and damage measures. We conducted two sets of multivariable analyses: the first examined education, income, or health literacy individually; the second included all three simultaneously. All multivariable models included age, sex, race/ethnicity, language, disease duration, and physician-assessed disease activity and damage.

Results: Over one-third (38%) had limited health literacy (LHL), including >25% with greater than high school education. In multivariable analyses simultaneously considering education, income, and health literacy, LHL was associated with significantly worse scores on all PROs except disease damage. In contrast, disparities by income were seen in only three PROMIS scales, three SF-36 subscales, and one disease activity measure. No disparities by education level were noted.

Conclusions: We found significantly worse PRO scores among individuals with LHL, even after controlling for disease activity and damage. Whether disparities are due to actual differences in health or measurement issues requires further study.

Patient-reported outcomes (PROs) play a prominent role in evaluating patient status in rheumatic diseases, including SLE. Studies have consistently revealed disparities in clinically-measured disease status and outcomes for individuals with low education or low

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income, and in many cases for individuals from racial/ethnic minorities (1–4). These disparities have been echoed in PROs (5).

An additional factor that has rarely been considered as a source of disparities is health literacy, defined as the degree to which individuals can obtain, communicate, process, and understand the basic health information and services they need to make appropriate health decisions (6). Low health literacy may lead to difficulties in patient-physician communication, understanding treatment protocols, and disease management, as well as greater healthcare utilization and poorer health outcomes (7–10). The prevalence of limited health literacy may be as high as 36% (11). Low health literacy is more prevalent among vulnerable population groups such as those with low education or racial/ethnic minorities, but simply relying on education or minority status as an indicator of low health literacy leads to misclassification of health literacy status in a substantial proportion of patients (12).

Health literacy may have unique effects on the assessment of PROs. Many PRO instruments are not evaluated for reading level or assessed for comprehension by patients with low levels of health literacy prior to widespread implementation. For example, patients with limited health literacy have more confusion about completing global assessments of rheumatoid arthritis (13), yet the global assessment is routinely used in clinical assessments. As a result, we do not have a clear understanding of how health literacy may affect responses to commonly used PROs. The goal of this analysis is to evaluate the impact of limited health literacy on PROs in a diverse SLE cohort and to put that impact into context with the more established impact of poverty and low levels of education.

Methods

Subjects

Subjects were participants in the California Lupus Epidemiology Study (CLUES), a multi-racial/ethnic cohort of individuals with physician-confirmed SLE. Some participants (n= 171) were recruited from the California Lupus Surveillance Project (CLSP), a population-based cohort of individuals with SLE living in San Francisco County from 2007 to 2009 (14). Additional participants (n= 260) residing in the nine counties in the San Francisco Bay Area geographic region were recruited through local academic and community rheumatology clinics and through existing local research cohorts. There were no substantive differences between the two groups in distribution of socio-demographic or clinical characteristics. In addition to residence in the San Francisco Bay Area, other inclusion criteria were a confirmed SLE diagnosis; oral language fluency in English, Spanish, Cantonese, or Mandarin; age ≥18 years; and ability to provide informed consent.

Study procedures involve an in-person research clinic visit, which includes collection and review of medical records prior to the visit; a history and physical examination conducted by a physician specializing in lupus; collection of biospecimens for clinical and research purposes; and completion of a structured interview administered by an experienced research assistant. All SLE diagnoses were confirmed by study physicians according to any of the following definitions: (a) the patient met ≥ 4 of the 11 ACR revised criteria for the classification SLE as defined in 1982 and updated in 1997, (b) the patient met ≥3 of the 11

ACR criteria plus a documented rheumatologist's diagnosis of SLE, or (c) the patient had a confirmed diagnosis of lupus nephritis. CLUES specifically aimed to include a diverse patient sample, with representation from the four largest U.S. racial/ethnic groups. Study visits and interviews were conducted in English, Spanish, Mandarin, or Cantonese.

A subgroup of participants was unable to attend the in-person visit (n = 37 (22%) from CLSP and n = 62 (24%) from additional Bay Area recruits). For these individuals, medical records were collected, and the same structured interview was administered by telephone. Diagnoses were confirmed through medical record review. For the current analysis, only individuals who participated in the in-person study visits were eligible (total n = 332; 134 from CLSP and 198 from Bay Area recruits).

Variables

Health literacy.—Health literacy was estimated with three questions developed by Chew et al. (15):

1. (1) How often do you have problems learning about your medical condition because of difficulty understanding written information? Never, rarely, sometimes, usually, always;
2. (2) How often do you have someone like a family member, friend, hospital or clinic worker or caregiver help you read health plan materials, such as written information about your health or care you are offered? Never, rarely, sometimes, usually, always; and
3. (3) How confident are you filling out medical forms by yourself? Not at all, a little bit, somewhat, quite a bit, extremely.

This measure has been validated against the Short Test of Functional Health Literacy in Adults (sTOFHLA)(16) for English and Spanish speakers, but not for Mandarin or Cantonese speakers. Correspondence of each item with the sTOFHLA categorization of marginal or inadequate health literacy using an area under the receiver operatory curve (AUROC) analysis ranged from 0.66 to 0.70 for English-speakers and 0.71 to 0.80 for Spanish speakers. Using a summative scale with a cut-point ≥ 9, intended to correspond to answers of "sometime" or "somewhat on all three questions, yielded an AUROC of 0.73 and 0.82 for English- and Spanish-speakers, respectively. For our analyses, any participant who responded "sometimes," "usually," or "always" to items 1 or 2, or "somewhat," "a little bit," or "not at all" to item 3 was classified as having limited health literacy.

Patient-reported outcomes

Patient Reported Outcomes Measurement Information System (PROMIS).—Ten PROMIS short forms were administered as part of the structured interviews. Physical Function, Pain Interference, Fatigue, and Sleep Disturbance were available in all languages. Sleep Impairment, Applied Cognitive Abilities, Ability to Participate in Social Roles and Activities, Satisfaction with Participation in Discretionary Social Activities, Satisfaction with Participation in Social Roles, and Social Isolation were available only in English and Spanish.

All scales were scored as recommended and converted to T-scores, with a population mean of 50 and standard deviation (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. For example, higher Physical Function and Satisfaction with Social Roles scores would reflect better functioning and satisfaction, so would be considered "better" scores; higher Fatigue, Pain Interference, Sleep Disturbance, Depression, and Anxiety scores would be considered "worse."

Medical Outcomes Study Short Form 36 (SF-36).—The SF-36 is widely used in SLE and includes 8 subscales: Physical Function, Role Physical, Role Emotional, Vitality, Mental Health, Social Function, and Bodily Pain (17). Scores for each scale range from 0 – 100, with a population mean of 50 and SD of 10. Higher scores for each scale reflect better outcomes. Validated versions of the SF-36 exist in English, Spanish, Cantonese, and Mandarin.

SLE-specific PROs.—SLE disease activity was measured with the Systemic Lupus Activity Questionnaire (SLAQ) (18, 19), a validated, self-report measure of SLE disease activity. Scores can range from 0 – 44, with higher scores reflecting more disease activity. The SLAQ also includes a final item, not included in the total SLAQ score, for respondents to rate the activity of their lupus over the past 3 months (0 [no activity – 10 [high activity]). The Brief Index of Lupus Damage (BILD) was used to estimate organ damage (20). The BILD is based on Systemic Lupus International Cooperating Clinics/American College of Rheumatology Damage Index (SDI) (21), and consists of 28 items capturing information on 26 SDI items including determinations of important comorbid conditions such as cardiovascular disease and events and diabetes. Scores can range from 0 – 46. The translations for SLAQ, SLE activity, and BILD were performed and tested by our group.

Other variables

The Systemic Lupus Erythematosus Disease Activity Index-(SELENA-SLEDAI) (22) and SDI (21) were completed by physicians as part of the research clinic visit. Age at lupus diagnosis was obtained during the physician examination. Race, ethnicity, age, household income, and education level were self-reported. Language was categorized by the language in which interviews were conducted (English, Spanish, Mandarin, or Cantonese). Current medications were recorded during interviews and confirmed during physician interviews. The following medications were classified as immunosuppressive agents: azathioprine, mycophenolate, methotrexate, cyclosporine, leflunomide, cyclophosphamide, any tumor necrosis factor inhibitor, or rituximab. Dose of prednisone or other glucocorticoids was also collected. Dosages of glucocorticoids other than prednisone were converted to prednisone-equivalent dosages. High-dose prednisone was defined as ≥7.5 mg per day for at least three months in the past year.

Statistical analysis

Bivariate analyses examined differences in demographic and clinical characteristics by health literacy (limited vs. not limited). Because low levels of education, low income, and limited health literacy are closely intertwined, differences were also examined by education

(≤12 years [low education] vs. >12 years) and income (≤125% of the federal poverty index for household size [low income] vs. >125%). Because over ten percent of the participants declined to provide income (34 of 323, 10.5%), a dummy variable for missing income was created and used as a third income variable in analyses. Bivariate analyses then examined differences in all PROs by health literacy, education, and income, using t-tests (health literacy and education) and analyses of variance (3 levels of income: below poverty, not below poverty, missing).

Multivariable linear regression analyses were then conducted to examine the association of limited health literacy, low income, and low education with PROs, first in separate models and second in a single model including all three. All models also included age, sex, race/ethnicity, language, disease duration, SLEDAI, and SDI.

Sensitivity analyses were conducted first excluding individuals with a history of cognitive impairment or possible current cognitive impairment noted during the physician evaluation, and second using alternative methods of identifying limited health literacy. Alternative methods were based on findings from Sarkar et al, in which the summative score of the three items dichotomized with a score of 9 and the single item regarding confidence with completing medical forms exhibited the greatest correspondence to the sTOFHLA (16).

P-values ≤0.05 were considered statistically significant. All analyses used SAS 9.4 (Cary, NC).

Results

Nine participants did not complete the health literacy items, resulting in n=323 for analyses. The sample was 89% women, with a mean age of 45 years and mean disease duration of 16 years (Table 1). The sample was diverse, with 36% Asian, 29% non-Hispanic white, 23% Hispanic, 11% black, and 2% other. Interviews were conducted primarily in English (86%). Nineteen percent had household incomes below poverty and 23% had a high school education or less. Thirty-eight percent of the cohort met the criterion for limited health literacy, including >25% with greater than high school education. Responses on each item of the health literacy assessment indicative of limited health literacy ranged from 21% to 24% (Table 2).

Differences in sociodemographic characteristics were seen by income, education, and health literacy, and illustrated the inter-relationships of income, education, and health literacy (Table 1). Individuals with low incomes and low education were less likely to be non-Hispanic white, had lower percentages of English interviews, and were more likely to have low health literacy. Participants with limited health literacy were more likely to be non-white, non-English speaking, and to have low education and low income. There were fewer differences in disease-related characteristics, although those with lower income and education had disease of shorter duration. Individuals with low income had greater disease damage (i.e., higher SDI scores), and those with low education were more likely to be currently using glucocorticoids and high doses of glucocorticoids. There were no significant differences in disease duration, medications, SLEDAI, or SDI by health literacy.

Statistically significant differences in PROs by income were noted for five of ten PROMIS scales, six of eight SF-36 scales, and all three SLE-specific PROs in bivariate analyses (Table 3). Significant differences by education were noted for only two PROMIS scales (Physical Function and Cognitive Ability), two SF-36 scales (Physical Function and General health), and two SLE-specific scales (SLAQ and SLE activity rating). Significant differences by health literacy were seen for all PROs. In all cases, when differences existed, those with low education, low income, or limited health literacy had worse scores.

In multivariable analyses, these patterns persisted (Table 4). In separate models including covariates plus only low education, low income, or limited health literacy, individuals with low incomes had worse scores on five of ten PROMIS scales and all eight SF-36 scales. Low education was associated with significantly worse scores on only the PROMIS Pain Interference and Cognitive Ability and the SF-36 Pain and General Health scales. In contrast, those with limited health literacy had worse scores on all PROMIS and SF-36 scales. For the SLE-specific scales, those with low education, low income, and limited health literacy each had significantly worse scores on the SLAQ and SLE activity rating, and no significant differences were noted for the BILD.

Finally, in the multivariable analyses that included low education, low income, and limited health literacy in the same models, low income was associated with worse scores on three of the PROMIS scales, three of the SF-36 scales, and SLE activity rating, while PRO scores did not differ by education status. In contrast, individuals with limited health literacy had significantly worse scores on all PROs except BILD (Table 5).

Sensitivity analyses.

Twenty-one individuals were identified during the clinical in-person visit with possible NPSLE, 11 with limited health literacy and 10 without. When these individuals were excluded from analyses, there were no substantive differences in the results (results not shown). When alterative scoring methods were used, fewer individuals were classified as having limited health literacy: 49 with the summative score using a cut-point of 9, and 68 using the single “forms” question. Agreement between the primary definition of limited health literacy and the alternative methods was 77% and 83%, for the summative and single item methods, respectively. In each case, lack of agreement was due to individuals being identified as having limited health literacy by the primary definition but not the alternative definition (n = 74 for the summative method and 55 for the single item). Multivariable results using the alternative scoring methods are shown in the Appendix. The results were substantively similar although differences between the health literacy groups on some individual scales were no longer statistically significant.

Discussion

In this diverse SLE cohort, we found substantial differences in PROs based on income and health literacy, but not low education. However, when both income and health literacy were considered simultaneously, in addition to low education and other covariates, differences in PROs by health literacy were the most striking. Individuals with limited health literacy had worse status as measured by all PROs except disease damage, even after accounting for physician-assessed disease activity and damage (SLEDAI and SDI), disease duration, age, sex, income, education, language, and race/ethnicity. Minimally important differences (MIDs) have been estimated for five of the PROMIS scales (Physical Function, Pain Interference, Fatigue, Participation in Social Roles, and Sleep Disturbance) in SLE (23). The decrements in scores for people with limited health literacy exceeded the MID estimate for each of these scales.

These findings are consistent with studies examining PROs among individuals with other health conditions. For example, low health literacy was associated with large, clinically significant decrements in Health Assessment Questionnaire (HAQ) scores among a large cohort of individuals with RA, even after accounting for educational attainment (9). Likewise, limited health literacy was associated with lower ratings of health status and quality of life among people with inflammatory bowel disease (IBD) (24). Other investigators have proposed that health literacy may at least partially mediate educational and racial/ethnic disparities in some health outcomes(25), but we found only limited evidence of such mediation in our analyses, because low education was much less frequently associated with the PROs, even without considering health literacy; i.e., there was little effect of low education to be mediated. Instead, our analysis indicated that even after controlling for race/ethnicity and education, limited health literacy was linked to worse PROs.

It is impossible to ascertain from these analyses whether the differences observed by health literacy status were due to actual differences in health status, to unmeasured effects of health literacy, or to difficulties understanding or interpreting the scale items. Although we did not observe significant differences between health literacy groups in physician-assessed disease activity or damage using the SLEDAI and SDI, limited health literacy may, indeed, have important effects on health. For example, it may affect the ability of patients to follow written instructions for medications (26) or engage in self-care, and it has been linked to nonadherence to medications (9). The association of limited health literacy with worse scores on PROs noted in the study of patients with IBD, also found that patients with limited health literacy had more symptoms of active disease (24). In rheumatoid arthritis, limited health literacy has been associated with health outcomes, poorer functional status, and more healthcare use (9, 10, 27).

Limited health literacy may affect assessments of disease activity as well as patient-physician communication. Patients with limited health literacy are more likely to report difficulty communicating with their providers and that the providers do not explain their condition or treatments in an understandable way (7). In rheumatoid arthritis, health literacy is associated with discrepancy between patient and physician global assessments (28). Hirsh reported that patients with low health literacy had difficulty responding to the patient global assessment scale used to calculate standard measures of RA disease activity such as the Disease Activity Scale 28 (DAS28), which may affect their reaching low disease states or remission by these measures as well as treatment choices (13).

Our findings, combined with those of other researchers, lead to critical questions of how to address limitations in health literacy in clinical and research settings. Clinically, Hirsh and colleagues recently reporting testing the Health Literacy Universal Precautions Toolkit to improve medication adherence among rheumatoid arthritis patients(29). This toolkit shifts the focus from trying to identify patients with limited health literacy to assuming that all patients have such limitations and incorporates three strategies: encouraging questions with specific text, implementing a “teach-back” method of communication, and a “brown-bag” medication review, for which patients were encouraged to bring all of their medications to the visit. The intervention did not increase visit time, improved medication adherence, and decreased disease activity among African American and Hispanic patients Patient-facing materials such as low literacy information guides and decision-making materials have been implemented to improve patient-physician communication and shared decision making (30–32); these are likely to address gaps in communication and understanding due to limited health literacy, as well.

The measurement implications of the differences in PRO scores between individuals with and without limited health literacy cannot be under-estimated. Reading levels of grade 6 are generally recommended as the target for educational materials (33). It stands to reason that the same reading level is an appropriate target for PROs. Yet, many of the PROs regularly used require higher reading levels or have not been evaluated. For example, the reading level of the SF-36 has been estimated at grade 8 (34). While evaluation of PROMIS items was stated to include assessments of reading levels (35), there is no published information on reading level of short forms.

This study does have limitations. In this study, we assessed health literacy using a brief self-report scale rather than longer, more complete assessments of health literacy such as the TOFHLA or Rapid Estimate of Adult Literacy in Medicine (REALM). The measure we used also focuses on literacy for written materials rather than the broader range of literacy. Of primary importance, it does not address communication, which may mediate a relationship between limited health literacy and poor outcomes. The measure has not been validated among Cantonese or Mandarin speakers, but has been validated against the TOFHLA for both English and Spanish speakers(15, 16). We were unable to stratify analyses by language because of the small number of non-English speakers, but multivariable analyses did control for language. Overall, our sample is relatively well educated, although education is not an adequate proxy for health literacy. Over 25% of those with more than a high school education met the criterion for limited health literacy. Patients with the lowest levels of literacy may not have responded to recruitment attempts or may have declined to participate because of intimidation by the study procedures or embarrassment (26). However, as data were collected by in-person interviews rather than self-administered questionnaires, this bias may have been somewhat mitigated. In other words, it is possible that the differences by health literacy levels may have been even greater if PROs had been self-administered (36). Many people with SLE have cognitive dysfunction, which may have affected understanding of directions or questions or the responses. We did not have measures of cognitive function, so were unable to test this potential relationship, although we did conduct a sensitivity analysis excluding individuals with documented NPSLE, which showed no substantial differences from the primary analyses. There may be other variables that influence PRO responses, such as fibromyalgia or other comorbidities, for which we were unable to adjust.

Balancing study limitations, there are several strengths to this study. It is the first to examine the issue of limited health literacy in SLE, a condition that is more prevalent among racial and ethnic minorities among whom we found high rates of limited health literacy. In addition, this study examined the most comprehensive set of PROs that has previously been considered, including both generic and disease-specific PROs. The study examined health literacy independent of education and income. We also examined alternative scoring methods to identify limited health literacy. Although some differences between literacy groups were no longer statistically significant with the alternative classification methods, the results were substantively similar. It is possible that the smaller number of individuals classified as having limited health literacy using the alternative methods may have contributed to differences found in results of these sensitivity analyses.

Conclusions

We found significantly worse PRO scores on all measures examined among individuals with limited health literacy. Whether differences are due to actual differences in health or to measurement issues such as differential understanding or interpretation of PROs by individuals with limited health literacy is unknown. However, we found these consistent differences even after controlling for physician-assessed SLE disease activity and damage. It seems, then, more likely that the observed differences may be due to measurement issues, although the effects of unmeasured covariates cannot be ruled out. Future PRO development and validation studies will need to carefully examine the possibility of differential item functioning by health literacy to attempt to answer this question. Overall, however, our findings suggest that attention to health literacy is crucial in the development, validation, and use of PROs to ensure that variation in scores reflect actual differences in the underlying construct and not differential understanding or interpretation of questions.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Significance and Innovation

- Individuals with limited health literacy had significantly worse PRO scores, even after controlling for education, income, and other covariates.
- The differences we noted may have been even greater if PROs had been self-administered instead of administered by an interviewer.
- Whether disparities in scores by health literacy status are due to actual differences in health or to measurement issues is an important consideration for both use and development of PROs.

Table 1.

Sample characteristics total and by income, education, and health literacy

		Income below poverty				Low education			Limited health literacy		
	Total (n = 323)	No (n=233)	Yes (n=56)	Not reported (n=34)	p	No (n=249)	Yes (n=73)	p	No (n=200)	Yes (n=123)	p
Sociodemographic											
% women	88.9 (287)	90.1 (210)	87.5 (49)	82.4 (28)	.38	89.2 (222)	87.7 (64)	.68	87.5 (175)	91.1 (112)	.37
Age	45.3 ± 13.9	45.7 ± 13.7	45.6 ± 13.8	41.6 ± 15.5	.27	44.4 ± 13.7	47.8 ± 14.6	.08	44.1 ± 13.7	47.3 ± 14.1	.05
Race/ethnicity[a]					.0004			.0006			.07
White	29.4 (95)	36.1 (84)	8.9 (5)	17.7 (6)		34.9 (87)	9.6 (7)		35.0 (70)	20.3 (25)	
Hispanic	22.6 (73)	19.7 (46)	37.5 (21)	17.7 (6)		19.7 (49)	32.9 (24)		19.5 (39)	27.6 (34)	
Black	10.5 (34)	7.7 (18)	19.6 (11)	14.7 (5)		9.2 (23)	15.1 (12)		9.5 (19)	12.2 (15)	
Asian	35.6 (115)	34.8 (81)	32.1 (18)	47.1 (16)		34.1 (85)	41.1 (29)		34.0 (68)	38.2 (47)	
Other	1.9 (6)	1.7 (4)	1.8 (1)	2.9 (1)		2.0 (5)	1.4 (1)		2.0 (4)	1.6 (2)	
Language of interview					<.0001			<.0001			<.0001
English	86.1 (278)	91.4 (213)	62.5 (35)	88.2 (30)		96.8 (241)	49.3 (36)		93.5 (187)	74.0 (91)	
Spanish	6.2 (20	3.9 (9)	19.6 (11)	0							
Cantonese, Mandarin	7.7 (25)	4.7 (11)	17.9 (10)	11.8 (4)							
Below poverty[b] (n=289)	19.4 (56)	---	---		---	10.2 (23)	52.4 (33)	<.0001	9.9 (18)	35.5 (38)	<.0001
Low education[c] (n=322)	22.7 (73)	12.9 (30)	58.9 (33)	30.3 (10)	<.0001	---	---	---	9.5 (19)	44.3 (54)	<.0001
Limited health literacy	31.9 (103)	29.6 (69)	67.9 (38)	47.1 (16)	<.0001	27.3 (68)	74.0 (54)	<.0001	--	---	---
Disease-related											
Disease duration, years	16.4 ± 10.6	17.4 ± 10.7	13.2 ± 9.1	15.0 ± 10.8	.02	17.1 ± 10.5	14.0 ± 10.2	.03	17.2 ± 11.0	15.2 ± 9.7	.08
Current use of immunosuppressive[d]	50.5 (163)	48.5 (113)	53.6 (30)	58.8 (20)	.47	49.0 (122)	56.2 (41)	.29	49.0 (98)	52.9 (65)	.57
Current use of prednisone	50.8 (164)	48.1 (112)	57.1 (32)	58.8 (20)	.29	46.6 (116)	64.4 (47)	.008	48.0 (96)	55.3 (68)	.21
High dose prednisone [e]	25.4 (81)	23.3 (54)	34.0 (18)	26.5 (9)	.34	22.2 (55)	35.7 (25)	.03	23.6 (47)	28.3 (34)	.36
SLEDAI[f]	3.0 ± 3.1	2.8 ± 3.1	3.5 ± 3.4	3.2 ± 2.6	.34	2.9 ± 2.5	3.5 ± 2.8	.10	3.0 ± 2.9	3.1 ± 3.4	.76
SDI[g]	1.9 ± 2.0	1.6 ± 1.8	2.6 ± 2.3	2.2 ± 2.5	.003	1.8 ± 2.0	2.0 ± 2.1	.59	1.7 ± 1.9	2.1 ± 2.3	.08

Tabled values are mean ± standard deviation or % (n).

p-values are from t-tests, analyses of variance, or chi-square analyses.

[a] Hispanic ethnicity was assessed separately from race. However, the majority of people of Hispanic ethnicity choose “other” as their race, and when queried respond “Hispanic” or “Latino/Latina” or with their country of origin (e.g., Mexican). Because of this, we simply report Hispanic as a separate category.

[b] Below poverty = income below 125% of federal poverty guidelines based on income and household size. 34 participants declined to provide income information.

[c] Low education = ≤12 years

[d] Immunosuppressive medications include: imuran, mycophenylate, methotrexate, cyclosporine, leflunomide, cyclophosphamide, any tumor necrosis factor inhibitor, or rituximab

[e] High dose prednisone was defined as:≥7.5 mg/day for ≥3 months in the past year.

[f] SLEDAI = Systemic Lupus Erythmatosus Disease Activity Index

[g] SDI = Systemic Lupus International Cooperating Clinics/American College of Rheumatology Damage Index

Table 2.

Responses to health literacy items (n = 323)

	Limited health literacy					
	Never	**Rarely**	**Sometimes**	**Usually**	**Always**	**Total limited**
How often do you have problems learning about your medical condition because of difficulty understanding written information	49.2% (159)	26.6% (86)	15.5% (50)	2.8% (9)	5.9% (19)	24.1% (78)
How often do you have someone like a family member, friend, hospital or clinic worker or caregiver help you read health plan materials, such as written information about your health or care you are offered?	61.6% (199)	15.5% (50)	10.8% (35)	4.6% (15)	7.4% (24)	22.9% (74)
	Extremely	Quite a bit	Somewhat	A little bit	Not at all	
How confident are you filling out medical forms by yourself?	62.1% (200)	16.8% (54)	11.5% (37)	4.7% (15)	5.0% (16)	21.1% (68)

Table 3.

Bivariate comparisons of PROs by income, education, and health literacy

		Income below poverty				Low education			Limited health literacy		
	n	No	Yes	Missing		No	Yes		No	Yes	
PROMIS											
Physical Function	323	48.9 ± 9.6	44.0 ± 10.2	46.5 ± 9.6	**	48.4 ± 9.6	45.9 ± 10.5	*	49.7 ± 9.5	44.6 ± 9.8	***
Pain Interference†	320	51.4 ± 9.6	55.0 ± 11.0	53.9 ± 11.1	*	51.8 ± 9.5	53.8 ± 11.5		50.6 ± 9.3	55.0 ± 10.8	**
Fatigue†	320	52.2 ± 11.7	52.4 ± 12.1	54.5 ± 12.5		52.7 ± 11.4	51.2 ± 12.9		50.6 ± 11.3	55.4 ± 12.0	**
Sleep Disturbance†	322	52.0 ± 8.2	54.6 ± 10.6	52.2 ± 11.3		52.1 ± 8.5	53.7 ± 10.7		51.0 ± 8.9	54.9 ± 8.8	**
Sleep Impairment†	298	52.4 ± 10.9	55.2 ± 11.7	55.2 ± 10.6		53.0 ± 10.8	53.6 ± 12.0		50.9 ± 10.7	57.3 ± 10.6	***
Cognitive Ability	297	48.7 ± 8.9	47.0 ± 7.4	46.7 ± 7.2		48.9 ± 8.7	45.4 ± 6.9	**	50.2 ± 8.7	44.6 ± 6.7	***
Participation in Social Roles	282	51.5 ± 9.3	47.0 ± 11.0	51.1 ± 10.4	*	50.9 ± 9.5	50.0 ± 11.3		52.4 ± 9.8	47.6 ± 9.2	***
Satisfaction with Discretionary Social Roles	297	53.5 ± 9.8	49.9 ± 10.3	52.7 ± 10.2		53.2 ± 10.0	51.4 ± 9.8		54.5 ± 9.7	49.9 ± 9.7	**
Satisfaction with Social Roles	295	51.8 ± 10.3	47.3 ± 10.6	51.7 ± 11.9	*	51.4 ± 10.5	49.9 ± 11.1		53.1 ± 10.2	47.5 ± 10.3	***
Social Isolation†	292	45.3 ± 8.5	50.4 ± 9.8	46.1 ± 10.3	**	46.1 ± 8.9	46.7 ± 9.9		44.4 ± 8.6	49.5 ± 9.1	***
SF-36											
Physical Function	323	45.1 ± 11.5	38.5 ± 13.2	41.7 ± 12.0	**	44.4 ± 11.6	41.1 ± 13.1	*	46.1 ± 11.0	39.4 ± 12.8	***
Role Physical	322	44.9 ± 10.8	41.3 ± 11.7	41.1 ± 11.3	*	43.9 ± 10.7	43.5 ± 12.2		45.6 ± 10.9	41.0 ± 10.8	**
Pain	322	47.5 ± 10.6	43.8 ± 11.6	46.1 ± 11.7		47.2 ± 10.4	45.1 ± 12.6		48.1 ± 10.4	44.4 ± 11.5	**
General Health	320	40.7 ± 11.8	35.2 ± 12.1	39.1 ± 10.7	**	40.5 ± 11.8	36.5 ± 11.7	*	41.7 ± 11.8	36.0 ± 11.2	***
Vitality	322	48.1 ± 12.1	46.5 ± 12.3	46.8 ± 12.6		47.5 ± 11.9	48.5 ± 13.2		49.2 ± 12.1	45.3 ± 12.1	**
Social functioning	322	46.2 ± 10.7	39.6 ± 13.4	43.8 ± 12.0	**	45.3 ± 10.6	43.1 ± 14.2		46.8 ± 10.6	41.6 ± 12.3	***
Role Emotional	321	47.1 ± 10.4	42.3 ± 12.7	42.9 ± 13.6	**	46.1 ± 11.3	45.2 ± 11.4		48.5 ± 9.7	41.5 ± 12.5	***
Mental Health	322	50.3 ± 9.5	44.9 ± 11.9	48.1 ± 11.6	**	49.5 ± 10.0	47.9 ± 11.7		51.2 ± 9.4	45.7 ± 10.9	***
Lupus-specific PROs											
BILD†	323	1.72 ± 1.99	2.57 ± 2.21	2.47 ± 2.83	**	1.95 ± 2.25	1.86 ± 1.76		1.76 ± 2.07	2.25 ± 2.26	*
SLAQ†	323	8.2 ± 6.9	11.4 ± 8.7	10.5 ± 7.8	**	8.5 ± 7.1	10.8 ± 8.0	*	7.8 ± 6.8	11.1 ± 7.9	***
SLE activity†	323	2.9 ± 2.4	4.7 ± 2.9	3.4 ± 2.6	***	3.0 ± 2.4	4.2 ± 2.9	**	2.8 ± 2.3	4.0 ± 2.8	***

For all scales except those noted by †, lower scores are worse.

Differences in sample sizes across scales was due primarily to language availability. Physical Function, Pain Interference, Fatigue, and Sleep Disturbance were available in all languages. Sleep Impairment, Applied Cognitive Abilities, Ability to Participate in Social Roles and Activities, Satisfaction with Participation in Discretionary Social Activities, Satisfaction with Participation in Social Roles, and Social Isolation were available only in English and Spanish.

p-values from analyses of variance (income) and t-tests (education, health literacy).

[*] $p<.05$

[**] $p<.01$

[***] $p<.0001$

BILD = Brief Index of Lupus Damage; SLAQ = Systemic Lupus Activity Questionnaire; SLE = systemic lupus erythematosus

Table 4.

Multivariable adjusted beta parameter estimates for comparisons of PROs by income, education, and health literacy

	Separate regression models for income, education, and health literacy			Single regression model including income, education, and health literacy		
	Income below poverty	**Low education**	**Limited health literacy**	**Income below poverty**	**Low education**	**Limited health literacy**
PROMIS						
Physical Function	**−4.3****	−2.7	**−4.2****	**−3.2***	−0.5	**−3.4****
Pain Interference†	**3.5***	**3.4***	**4.4****	2.2	1.5	**3.5****
Fatigue†	1.1	0.4	**5.5*****	−0.02	−1.8	**5.5****
Sleep Disturbance†	2.9	2.6	**4.2****	0.8	0.7	**3.8****
Sleep Impairment†	3.1	1.3	**6.6*****	1.8	−2.0	**6.6*****
Cognitive Ability	−1.4	**−4.1****	**−5.6*****	0.7	−2.1	**−5.4*****
Participation in Social Roles	**−5.2****	−2.1	**−4.8****	**−4.3***	0.9	**−4.4****
Satisfaction with Discretionary Social Roles	−3.0	−1.3	**−4.1****	−2.2	1.0	**−3.9****
Satisfaction with Social Roles	**−4.0***	−1.6	**−5.3*****	−2.9	1.3	**−5.1****
Social Isolation†	**5.9****	1.5	**5.4*****	**5.2****	−2.3	**5.0*****
SF-36						
Physical Function	**−5.5****	−3.3	**−5.8*****	**−4.1***	−0.3	**−4.9****
Role Physical	**−4.2***	−2.9	**−5.1*****	−3.0	−0.3	**−4.5****
Pain	**−3.7***	**−4.0***	**−4.0****	−2.4	−2.1	**−3.1***
General Health	**−4.8***	**−4.7***	**−5.6****	−3.1	−2.0	**−4.7****
Vitality	**−4.0***	−2.5	**−5.2****	−2.9	0.2	**−4.7****
Social functioning	**−6.6****	−2.6	**−5.3****	**−5.7****	0.8	**−4.7****
Role Emotional	**−4.9****	−2.4	**−7.3*****	−3.5	1.3	**−7.0*****
Mental Health	**−6.1****	−1.7	**−5.8*****	**−5.2****	1.8	**−5.4*****
SLE-specific PROs						
BILD†	0.24	−0.3	0.20	0.3	−0.5	0.2
SLAQ†	**2.5***	**2.4***	**2.8****	1.7	1.1	**2.1***
SLE activity†	**1.7*****	**1.2****	**1.0****	**1.4****	0.6	**0.7***

For all scales except those noted by †, lower scores are worse.

Bolded values are significant at p<.05.

*p<.05

**p<.01

***p<.0001

All analyses control for age, sex, race/ethnicity, language, missing income, disease duration, SLEDAI (Systemic Lupus Erythmatosus Disease Activity Index), and SDI (Systemic Lupus International Cooperating Clinics/American College of Rheumatology Damage Index)