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ORIGINAL ARTICLE

Assessment of Health-Related Family Role Functioning in Systemic Lupus Erythematosus: Preliminary Validation of a New Measure

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Objective. **Individuals with systemic lupus erythematosus (SLE) often experience symptoms that affect family relationships, which are important components of quality of life. To assess the impact of SLE on family role functioning, we developed a 6-domain (Fatigue, Activity participation, Mental health, Isolation, Love and intimacy, and You/fulfilling family roles [FAMILY]) measure. The objectives of this study were to pilot test and achieve preliminary validation for the SLE-FAMILY questionnaire.**

Methods. **This was a 3-phase study. In phase 1 (development), domains were identified and items were generated for evaluation. During phase 2 (pilot test), a pilot test was conducted to assess the performance of candidate items. In phase 3 (initial validation), 52 individuals with SLE completed questionnaires, including the 6-item SLE-FAMILY. Data were analyzed for internal consistency reliability, and validity was assessed using correlations between the SLE-FAMILY questionnaire and well-validated measures.**

Results. **The SLE-FAMILY had good test–retest reliability (0.82) and internal consistency (0.67). Reliability analysis of individual items revealed weakness in the performance of item 5. We reviewed raw data and determined that 9 individuals likely overlooked the reverse scoring of item 5, thus explaining its poor reliability. When these 9 individuals were excluded from analysis, Cronbach's alpha increased to 0.71, while test–retest reliability remained acceptable (0.75). Spearman's rho correlations supported the validity of the SLE-FAMILY measure. A pilot test of the SLE-FAMILY questionnaire without the reverse-scored item was conducted; results suggested that the modified version is superior to the initial form.**

Conclusion. **The SLE-FAMILY questionnaire is a promising new instrument for robust measurement of family role functioning.**

INTRODUCTION

Individuals with systemic lupus erythematosus (SLE) often contend with fatigue (1,2), pain (3), sleep disturbances (2,4), depression (1,3,5), and anxiety (6,7). Given the unpredictability of SLE, the severity of symptoms, and the fact that it affects young adults (8,9), a diminished ability to fulfill social roles within the family is expected; however, the extent of this social role disruption and potential impact on disease outcomes and psychological well-being may not be fully appreciated.

The few studies that have been conducted have shown that individuals with SLE greatly value their relationships with family and friends, but many report periodic or permanent effects of the disease on their daily activities at home and at work (10,11). Interference with daily activities due to impaired physical and psychological functioning can lead to social role dysfunction, i.e., the impaired

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Significance & Innovations

- Systemic lupus erythematosus (SLE) tends to strike individuals during childbearing years; therefore, the impact on family role functioning can be particularly profound and stressful for all involved.
- Existing measures of quality of life often do not tap into the unique aspects of family role functioning in most disease states.
- The SLE-FAMILY is a brief self-report questionnaire that provides a more granular assessment of family role functioning in the context of the unique concerns of individuals with SLE.

ability to fulfill key social roles such as spouse, parent, and worker. Social role dysfunction is thought to be central to impaired quality of life and has been found to mediate the relationship between SLE disease severity and psychological functioning (12).

Disruption of positive family relationships may be particularly problematic for people with SLE. In a study comparing individuals with SLE to those with rheumatoid arthritis, issues related to home and living environment were rated as more important by people with SLE (13). The high importance placed on family life by those with SLE may arise from an increased presence of young children in the home. SLE strikes primarily women of childbearing age and, compared to 20 years ago, there is far less concern about the risks to both mother and unborn child. Therefore, many with SLE strive to have a "normal" and fulfilling family life, but they may encounter multiple barriers due to the effects of the disease.

Understanding social role functioning within the family has not been well studied in SLE. This may be due in part to the fact that there is a lack of instruments that tap into this specific area. Given the importance of family to individuals with SLE and the key role of social support, it seems appropriate that such an instrument be developed. Therefore, in accordance with the objectives of this study to develop, pilot test, and achieve preliminary validation for a new measure, we developed the SLE-FAMILY (Fatigue, Activity participation, Mental health, Isolation, Love and intimacy, and You/fulfilling family roles) questionnaire to assess the impact of SLE on family role functioning.

PATIENTS AND METHODS

Study design. This study was conducted in 3 phases plus a small trial to assess the performance of a slightly modified version of the instrument. Phase 1 consisted of a literature review, a qualitative study, selection of domains to be associated with the SLE-FAMILY measure, and generation of items. During phase 2, a pilot test was conducted to assess performance of candidate items, as well as readability and comprehension of items and instructions. Based on these findings and patient feedback, the SLE-FAMILY measure was refined and finalized. Phase 3 consisted of a validity trial where the SLE-FAMILY questionnaire and validated measures were administered to 52 SLE patients. One week later patients completed the SLE-FAMILY questionnaire a second time to evaluate test–retest reliability. Seven of the 52 patients completed cognitive interviews. Upon completion of phase 3, a small trial to assess the performance of a slightly modified version of the instrument was conducted.

Phase 1: instrument development. *Participants.* Twenty patients from the rheumatology clinic of the University of Medicine and Dentistry of New Jersey-Robert Wood Johnson Medical School (UMDNJ-RWJMS) completed qualitative interviews. All participants met American College of Rheumatology (ACR) criteria for SLE (14), were between ages 20 and 65 years, and were fluent in English. This study was approved by the Institutional Review Board at UMDNJ-RWJMS. All participants completed a consent form and received a $30 subject fee. No patient could participate in more than one phase of this study. Demographic information appears in Table 1.

Table 1. Characteristics of samples from all 3 study phases and the followup pilot study*

	Phase 1: interviews (n = 20)	Phase 2: pilot study (n = 25)	Phase 3: validation (n = 52)	Followup pilot (n = 15)
Female, % (no.)	90.0 (18)	96.0 (24)	88.5 (46)	88.1 (59)
Age, mean ± SD years	38.0 ± 11.5	39.1 ± 11.6	36.8 ± 11.9	38.9 ± 12.6
White non-Hispanic, % (no.)	60.0 (12)	29.2 (7)	33.3 (17)	34.8 (23)
Married, % (no.)	50.0 (10)	43.5 (10)	34.6 (18)	38.8 (26)
Duration of SLE, mean ± SD years	10.3 ± 7.2	7.8 ± 5.2	8.4 ± 6.7	8.4 ± 6.3
SLE <2 years, % (no.)	25.0 (5)	14.3 (3)	24.5 (12)	13.3 (2)
SLAQ score, mean ± SD	–	16.9 ± 8.7	13.6 ± 9.2	–
Mild disease activity, % (no.) (SLAQ score <4 [1 SD below the mean])	–	24.0 (6)	19.2 (10)	–
Severe disease activity, % (no.) (SLAQ score >22 [1 SD above the mean])	–	20.0 (5)	17.3 (9)	–

* SLE = systemic lupus erythematosus; SLAQ = Systemic Lupus Activity Questionnaire.

Procedures. Based on an extensive review of the literature regarding SLE and study team expertise, a brief interview was developed and administered to 20 patients with SLE to identify themes or domains anticipated to play a role in health-related family role functioning. The interviews were brief (<10 minutes) and responses were noted verbatim. Interviewers (DCR and SVS) clarified the content of responses with patients when uncertain and were allowed to show them their notes for verification. The notes were transcribed and the 20 transcripts were independently scored by 2 expert raters (ALH and DCR). The two raters coded the content of the interviews by using a priori codes for themes and then using grounded coding to allow unidentified themes to emerge. The themes or domains were then coded based on the frequency of report and emphasis placed on the topic by patients. Highly emphasized content was denoted by an asterisk. Following these interviews, 2 of the SLE patients were invited to become members of the study team. Both individuals, one white man and one African American woman, were in their mid-30s and both were married with young children in the home. The patient advisors joined the study team on all conference calls in order to provide feedback in regard to the patient perspective throughout the course of instrument development, including identifying the themes or domains, item generation and evaluation, and finalizing the content and appearance of the SLE-FAMILY instrument.

Next, the study team generated several items for each of the 6 top priority domains and refined the most favored ones. Response options were established, instructions were drafted, and responses, instructions, and items were subjected to Flesch-Kincaid Grade Level readability tests to meet the goal of having content at no higher than an eighth-grade reading level. The instructions were crafted to intimate that "family" can be interpreted broadly, as it became clear during the course of the interviews that family can mean different things to different people. The instrument was formatted to use a 7-point numerical rating scale to indicate to what degree an item is true of the respondent at that time. The SLE-FAMILY pilot questionnaire consisted of 16 items, i.e., 2 or 3 items for each of the 6 domains.

Phase 2: pilot testing and instrument refinement. *Participants.* Twenty-five patients from the UMDNJ-RWJMS rheumatology clinic participated in the pilot trial. Consistent with phase 1, all participants met the ACR criteria for SLE (14), were between ages 20 and 65 years, were fluent in English, completed a consent form, and received a $30 subject fee. Their demographic information appears in Table 1.

Procedures. Participants completed a series of questionnaires including the 16-item SLE-FAMILY pilot questionnaire and a demographics form. The order of the questionnaires varied for each patient, although the SLE-FAMILY always appeared first. Patients were directed to read the instructions associated with the questionnaires, but no other explanations about completing them were offered. Patients were allowed to ask questions if the instructions were unclear. Inquiries related to the SLE-FAMILY measure were recorded to advise later edits to the questionnaire.

Phase 2 measures. In order to assess the performance of the items, the following well-validated measures were used.

Systemic Lupus Activity Questionnaire (SLAQ). The SLAQ is a self-report measure of disease activity (15). It contains 24 items related to disease activity in SLE (e.g., malar rash, fatigue, photosensitivity, and chest pain), as well as an item querying flares in the last 3 months and a numerical rating scale of disease activity. Scores range from 0–44.

Medical Outcomes Study Short Form 36 (SF-36). The SF-36 provides a physical composite summary score and a mental composite summary (MCS) score and addresses 8 health domains: 1) physical functioning, 2) role functioning, 3) bodily pain, 4) general health, 5) social functioning, 6) role and emotional functioning, 7) vitality (energy versus fatigue), and 8) general mental health (16,17).

Sheehan Disability Scale (SDS). The SDS is a 5-item self-report instrument for the assessment of disability in 3 key areas (work/school, social life, and family life/home responsibilities), and 2 questions query days of missed work/school and days of feeling less productive (18).

Fatigue Severity Scale (FSS). The 9-item FSS is a self-report measure of fatigue severity, originally developed and validated for SLE and multiple sclerosis patient populations (19). Scores range from 1 (no fatigue) to 7 (severe fatigue). Scores ≥3 indicate that patients are experiencing fatigue, while scores ≥4 suggest that the fatigue is severe. The FSS has demonstrated good test–retest reliability, internal consistency, validity, and sensitivity to clinical change (19).

Satisfaction with Life Scale (SWLS). The SWLS is a 5-item self-report measure of global life satisfaction previously found to be valid and reliable (20,21). Scores <20 reflect levels of life satisfaction that are slightly below average, while scores >29 are associated with people who are very highly satisfied with their lives.

Positive and Negative Affect Scale (PANAS). The PANAS consists of 2 mood scales with 10 items each for the assessment of positive and negative affect. The scales have been shown to be internally consistent, uncorrelated, and stable over a 2-month period; good convergent and discriminant validity have also been demonstrated (22).

Multidimensional Scale of Perceived Social Support (MSPSS). The MSPSS is a 12-item questionnaire validated for the assessment of perceived social support (23). Respondents indicate to what degree they agree or disagree with statements like, "My family really tries to help me." A single global scale can be calculated, as well as 3 subscale scores for perceived social support from friends, family, and significant others.

Phase 2 analysis. Data were analyzed by grouping items by domain, with Cronbach's alpha calculated for each domain. Items for which the domain's alpha increased when they were dropped from the domain were elimi-

nated. Correlations for the remaining items and reference scales, both general and those specific to each domain, were used as a basis to select 1 item from each domain. Judgment regarding the final items included in the SLE-FAMILY questionnaire combined statistical analysis with the consensus of the development team, including the patient advisors.

Phase 3: assessment of validity and reliability. *Participants.* Fifty-two patients were recruited from the UMDNJ-RWJMS rheumatology clinic to participate in the validity study. As in the other phases, participants met the ACR criteria for SLE, were between ages 20 and 65 years, were fluent in English, completed a consent form, and received a $30 subject fee. Demographic information is presented in Table 1.

Procedures. Patients completed the same questionnaires used in phase 2. The questionnaires appeared in random order, although the SLE-FAMILY questionnaire always appeared first. Patients were instructed to read the directions associated with the questionnaires, but no other explanations about completing the questionnaires were offered. Seven of the phase 3 patients participated in a debriefing and face validity trial. Upon completion of the questionnaires, each consecutive patient was invited to participate in the interview until 7 patients were recruited. The semistructured interview consisted of questions that covered various topics, including the clarity of the instructions, item clarity, response options, and suggestions for other pertinent items. Also included were questions related to face validity for each of the 6 items. These patients received another $20 for their additional participation.

One week later all 52 respondents were asked to complete the SLE-FAMILY questionnaire a second time in order to assess test–retest reliability. This followup SLE-FAMILY questionnaire was collected by mail. Those who did not return the followup questionnaire in a timely manner received a phone call reminder. Participants who completed the followup SLE-FAMILY questionnaire were paid an additional $20 fee for their participation.

Phase 3 measures. The 6-item version of the SLE-FAMILY was used. This 6-item instrument has a single item to represent each of the 6 domains presumed to be associated with health-related family role functioning (Table 2). Responses are registered on a 7-point Likert scale anchored by phrases such as, "No limitations on my ability," "Some limitations on my ability," and "Completely limited my ability." A total score is achieved by summing the responses and dividing by the number of items with a response. Scores range from 1–7, with higher scores indicating worse family role functioning.

In order to assess the performance of the questionnaire, the same well-validated measures used in phase 2 were used in phase 3 as well (SF-36, SDS, FSS, PANAS, SWLS, and MSPSS). The same demographics form was also used.

Phase 3 analysis. Cronbach's alpha was used to assess internal consistency. Unidimensionality was assessed using an exploratory bifactor model, which features a comparison of a single factor model to a model with a general factor and group factors (24). Test–retest reliability was assessed using the intraclass correlation form (2,1) (25) of the total SLE-FAMILY scores from the 2 administrations. Item statistics were calculated to assess the correlations between individual items and the total score on the SLE-FAMILY questionnaire, while also correcting for item overlap and scale reliability by subtracting the item variance and replacing it with the estimated common variance (26). Construct validity of the SLE-FAMILY questionnaire was assessed via Spearman's rank correlations with the other measures.

Table 2. Reliability analysis of individual items (n = 52)*

Items	SLE-FAMILY total
1. Fatigue got in the way of the things that I needed to do for my family.	0.76
2. My SLE has been hard on my family emotionally.	0.63
3. My family excluded me from things because of my SLE.	0.69
4. My SLE got in the way of my developing or maintaining intimate relationships.	0.70
5. My SLE limited my ability to do all the things I wanted to do with my family.	−0.22
6. Despite my SLE I was able to fulfill my family roles.	0.59

* Values show the correlations between individual items and the total score on the SLE-FAMILY corrected for item overlap and scale reliability by subtracting the item variance and replacing it with the estimated common variance. SLE = systemic lupus erythematosus; FAMILY = Fatigue, Activity participation, Mental health, Isolation, Love and intimacy, and You/fulfilling family roles.

RESULTS

Phase 1 results. Participants consisted of 18 women and 2 men. Most reported moderate to high work and social life disability and moderate disruption in family and home life. The meaning of "family" varied as follows: 95% of patients listed immediate family members as their family, but 70% also included extended family, friends, and/or even pets. Most patients (60%) indicated that their lives were out of balance due to SLE and that work and other mandatory obligations often had to come before family. Similarly, 80% reported that SLE negatively impacted their ability to function properly in various family roles (e.g., mother/father, husband/wife, or "bread winner").

The most common themes or domains and their subthemes were: 1) fatigue: when asked about the most bothersome symptom of SLE, fatigue was most frequently volunteered (65%, n = 13) and was reported as problematic by 90% of SLE patients interviewed. Fatigue, even more so than pain, was cited as a major reason for not being able to participate in family activities; 2) family activity participation: 55% reported that flares were unpredictable, but in

contrast to what we anticipated, most patients learned how to cope with them. Instead of having concerns about planning ahead due to the unpredictability of the disease, "active" activities (especially outdoor activities requiring exposure to the sun or vigorous exercise) were reportedly greatly affected by SLE; 3) mental health: 88% reported that poor mental health impaired their ability to do the things that they liked to do with their families but, more importantly, the mental health and well-being of their entire family was affected by their SLE; 4) isolation versus social support: withdrawal tended to occur during disease flares when patients commonly noted that they would retreat to bed. However, feeling excluded by loved ones from valued activities and isolated by others was deemed more distressing; 5) intimacy and love: of the 19 sexually active participants, 84% reported that SLE had a negative impact on their ability to have a gratifying sex life. Close to half reported that this distanced them from their significant others; and 6) role functioning: 80% described ways in which family roles, especially those of spouse and parent, were adversely impacted by SLE.

Phase 2 results. Data from the 25 patients completing the SLE-FAMILY pilot questionnaire showed that 9 of the 16 items could be considered "strong" in that they contributed significantly to domain alpha and were highly correlated with the total SLE-FAMILY score based on all 16 items, as well as the SDS family subscale (Table 3). A single item for each of the 6 domains was selected based on those correlations and associations with measures of a similar construct from the validated instruments. More specifically, the fatigue item chosen had the strongest correlations with the SLAQ fatigue item and the FSS. The activities item selected was highly correlated with SF-36 social functioning and MSPSS family. The mental health item had the highest correlations with the SF-36 MCS and the SF-36 mental health domain. The strongest isolation item had the highest correlation with the SDS family, SDS social, the SWLS, and SF-36 role emotional. The love/loss of intimacy item was strongly correlated with SF-36 social functioning, SF-36 role emotional, and the SWLS. The you/social role item selected had a high correlation with SF-36 social role functioning and SDS family. The 6 chosen items combined as a single questionnaire had good internal consistency ($\alpha = 0.88$) and were highly correlated with SDS family item ($r = 0.89$) and SF-36 social functioning ($r = 0.88$).

Phase 3 results. Data from the 52 patients with SLE completing this phase showed that the SLE-FAMILY questionnaire had good test–retest reliability (0.82) and internal consistency (0.67). However, reliability analysis of individual items revealed a weakness in the performance of item 5 (Table 2). After reviewing the raw data, it appeared that 9 patients had likely overlooked the reverse direction of responses for item 5 (i.e., for all other items the response scale was shown with the most positive response on the far left and the most negative response on the far right. For item 5, the positive response was on the right and the negative on the left), therefore explaining its poor reliability. When the 9 patients were excluded from the analysis, alpha increased to 0.71, while test–retest reliability remained acceptable (0.75). Results from the assessment of unidimensionality using bifactor analysis and omitting participants with aberrant responses to item 5 showed that loadings for the general factor in the bifactor model shrank somewhat compared to the single factor model (a phenomenon previously observed) (24), but no variable's loading shrank by more than 16%. With just 6 items, 1 per domain, there could only be limited evidence for or against unidimensionality. Together, however, these results do not indicate any gross violation of unidimensionality.

Table 3. Individual item correlations with 6-item SLE-FAMILY total score and the family subscale of the Sheehan Disability Scale (SDS)*

Items	SLE-FAMILY total	SDS-family subscale
1. Because of my SLE I frequently missed important family activities.	0.72	0.64
2. Fatigue got in the way of the things that I needed to do for my family.	0.78	0.75
3. Concerns that I might have a disease flare made it difficult to plan family activities.	0.23	0.05
4. My family excluded me from things because of my SLE.	0.76	0.66
5. I felt like a burden to my family because of my SLE.	0.67	0.38
6. My SLE got in the way of my developing or maintaining intimate relationships.	0.83	0.76
7. My SLE limited my ability to do all the things I wanted to do with my family.	0.71	0.77
8. My SLE has been hard on my family emotionally.	0.77	0.69
9. Fatigue made it difficult for me to do all the family activities that I would like to do.	0.79	0.52
10. I felt that I was not able to contribute adequately to my family.	0.74	0.56
11. I felt isolated from my family because of my SLE.	0.56	0.33
12. My SLE caused me to feel less emotionally connected to my family members.	0.50	0.20
13. If I had less fatigue, I could have done so much more for and with my family.	0.75	0.70
14. My SLE got in the way of my having a gratifying sex life.	0.47	0.38
15. It troubled me that my family worried about my health and well-being.	0.58	0.66
16. Despite my SLE, I was able to fulfill my family roles.	0.75	0.64

* See Table 2 for definitions.

Spearman's rho correlations supported the validity of the SLE-FAMILY measure as its total score was significantly related to SDS family ($r = 0.67$, $P < 0.001$) and SDS social ($r = 0.60$, $P < 0.001$); MSPSS family ($r = -0.33$, $P < 0.031$); PANAS negative subscale ($r = 0.55$, $P < 0.001$); FSS ($r = 0.62$, $P < 0.001$); and the SLAQ ($r = 0.68$, $P < 0.001$). Similarly, the SLE-FAMILY total score was inversely related to relevant SF-36 subscales scores, including social functioning ($r = -0.55$, $P < 0.001$); role emotional ($r = -0.42$, $P < 0.005$); role physical ($r = -0.59$, $P < 0.001$); and mental health ($r = -0.48$, $P < 0.001$). Table 4 shows the mean ± SD, as well as the correlations for the SLE-FAMILY measure and other measures omitting the participants with aberrant responses to item 5 (n = 43).

Patients taking part in the cognitive interviews (n = 7) indicated that the instructions were easy to read and readily understandable. Also, 90% of the time, the 6 items were rated as 9 or 10 on a 10-point scale, where 10 represented an "excellent" item for the assessment of a particular domain. Moreover, in the comments section, every patient expressed the view that evaluating how SLE affected family role functioning was extremely important.

Followup pilot for the revised SLE-FAMILY measure. In the original sample, inspection of individual responses suggested that some respondents may have overlooked the reverse scoring pattern of item 5. Therefore, we conducted a small followup study to evaluate a version of the SLE-FAMILY questionnaire with item 5 scored in the same direction as the other items. Fifteen patients meeting the same recruitment criteria were recruited from the UMDNJ-RWJMS rheumatology clinic. Demographic information is presented in Table 1. Patients gave informed consent then completed the revised version of the SLE-FAMILY questionnaire (Supplemental Appendix A, available in the online version of this article at http://onlinelibrary.wiley.com/journal/10.1002/(ISSN)2151-4658). In this sample, which was given the nonreversed version of item 5, the individual patterns of scores were consistent across all items. The total of the other items was a reasonable predictor of the item 5 response ($r^2 = 0.61$) and the standardized alpha dropped slightly from 0.90 to 0.87 when item 5 was dropped. These results support our belief that some individuals overlooked the reverse scoring of item 5 and suggest that no reverse scoring gives better results on this instrument.

Table 4. Phase 3 results for the SLE-FAMILY measure and other measures omitting the participants with aberrant responding to item 5 (n = 43)*

Measure	Mean ± SD	Correlation predicted	Correlation observed
SLE-FAMILY total	3.5 ± 1.0	–	–
Fatigue (item 1)	4.4 ± 1.2	–	–
Activity participation (item 5)	4.1 ± 1.7	–	–
Mental health of entire family (item 2)	4.1 ± 1.8	–	–
Isolation (item 3)	2.2 ± 1.6	–	–
Love and intimacy (item 4)	3.2 ± 2.1	–	–
You/family role functioning (item 6)	3.5 ± 1.5	–	–
SLAQ total disease activity score	15.8 ± 8.5	+	0.676†
SDS family life/home responsibilities	5.5 ± 2.8	+	0.670†
SDS social life	5.7 ± 3.0	+	0.598†
MSPSS social support from family	5.9 ± 1.5	–	−0.330‡
Satisfaction With Life Scale	20.7 ± 7.7	–	−0.311‡
Fatigue Severity Scale	5.0 ± 1.3	+	0.0618†
PANAS positive affect	33.8 ± 6.4	–	−0.199
PANAS negative affect	21.6 ± 7.3	+	0.549†
Short Form 36 scores			
Physical component summary	49.1 ± 19.7	–	−0.570†
Mental component summary	53.9 ± 18.0	–	−0.549†
Physical functioning	53.6 ± 26.5	–	−0.550†
Role-physical	42.4 ± 43.9	–	−0.591†
Bodily pain	52.9 ± 29.1	–	−0.431†
General health	43.2 ± 22.9	–	−0.418†
Vitality	44.7 ± 20.2	–	−0.343‡
Social functioning	57.0 ± 28.9	–	−0.549†
Role-emotional	50.4 ± 47.9	–	−0.416†
Mental health	64.9 ± 20.5	–	−0.479†

* Correlations are for the SLE-FAMILY questionnaire total and other measures. SLAQ = Systemic Lupus Activity Questionnaire; SDS = Sheehan Disability Scale; MSPSS = Multidimensional Scale of Perceived Social Support; PANAS = Positive and Negative Affect Scale (see Table 2 for additional definitions).
† Correlation is significant at the 0.01 level (2-tailed).
‡ Correlation is significant at the 0.05 level (2-tailed).

DISCUSSION

The SLE-FAMILY questionnaire is a promising new instrument for the measurement of an important area of health-related quality of life, family role functioning. In the preliminary validation study, the 6-item SLE-FAMILY measure demonstrated good reliability and validity. A modification made to one of the items, changing the scoring direction to make it uniform with the other 5 items, was shown to further enhance the performance of the instrument. Each item on the SLE-FAMILY questionnaire was designed to give insight into 6 domains related to family role functioning: fatigue, activity participation, mental health, isolation, love and intimacy, and "you" (family role fulfillment). The total score provides a composite score based on these domains that relates to the construct of interest, the impact of SLE on family role functioning. We found that no other measure had a score with a stronger association with patient-assessed disease activity than did the SLE-FAMILY measure. The measure was also highly associated with self-report physical and mental health, satisfaction with life, and symptom severity. Although the SLE-FAMILY measure had a strong correlation with the SDS family scale supportive of its validity, it explained only 45% of the variation in the SDS family scale, suggesting the SLE-FAMILY measures something unique. Family role functioning could be a valuable and sensitive measure of key outcomes in SLE for a number of reasons.

Qualitative interviews conducted as part of this project highlighted the importance that individuals with SLE placed on their family relationships. People with SLE indicated that these relationships and their ability to function in the roles of spouse and parent were critical and often adversely impacted by SLE. Sixty percent reported that their lives were out of balance because SLE often forced them to choose work and other mandatory activities over family. Similarly, 80% reported that their ability to function properly in various family roles (e.g., mother/father, husband/wife, or "bread winner") is negatively affected by SLE. It seems that symptoms like pain and fatigue limit the resources available for functioning overall, and family activities such as going to a movie or attending a child's sporting event were foregone in order to address work-related demands and/or household chores. It has been previously shown in SLE that these valued life activities, which are central to good quality of life, can stop being a priority (27).

We also learned that the definition of family is highly individualized and can include others outside of the nuclear family (e.g., in-laws from a previous marriage, friends, and pets) whose relationships are highly valued and presumed to be affected by the patient's SLE. A consistent theme was how the symptoms of SLE, especially fatigue and sun sensitivity, interfered with the outdoor activities that patients most wanted to participate in with their families. Loss of participation in these and other activities was viewed as affecting the mental health of both patients and family members. Depression is common in SLE (1,3) and has been directly correlated with disease activity (6) and functional disability (1). It is unclear whether the increased rates of mood disorders in individuals are due to changes secondary to SLE, the result of persistent stress that stems from living with a chronic disease, and/or due to some other process (1,3,7). Nonetheless, the mental health and general well-being of many SLE patients and their families are compromised, and this can negatively affect these essential relationships.

The SLE-FAMILY measure assesses functioning in a unique but critical area, upon which individuals with the disease place a high value. While further validation studies remain to be conducted, we suggest that family role functioning, as measured by the SLE-FAMILY questionnaire, may prove to play an important role in overall psychological well-being among individuals with SLE. Further, such an instrument would likely prove to be a valid measure in many chronic disease conditions. While the SLE-FAMILY measure (Supplemental Appendix A, available in the online version of this article at http://onlinelibrary.wiley.com/journal/10.1002/(ISSN)2151-4658) was developed for those with SLE, the same instrument may require minimal or no revision for evaluating family-specific concerns in other populations.

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 submitted for publication. Dr. Hassett had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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ADDITIONAL DISCLOSURE

Dr. Li is currently employed by Daiichi Sankyo but was not at the time of the study. Daiichi Sankyo had no financial interest in this project and had no input in the design, content, data collection, or analysis, and had no role in the writing or approval of this article, with all opinions and conclusions expressed herein those of the authors.

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