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Treatment Satisfaction in Systemic Lupus Erythematosus
Development of a Patient-Reported Outcome Measure

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Objective: The aim of this study was to develop a patient-reported outcome measure specific for systemic lupus erythematosus (SLE) to assess patient satisfaction with treatment, treatment options, and medical care.

Methods: Patients with SLE were recruited from four US rheumatology practices. Concept elicitation interviews identified aspects that patients considered important and relevant regarding satisfaction with treatment and medical care. Concept elicitation interviews and clinical input were used to draft the Lupus Satisfaction Questionnaire (LSQ). A second cohort of patients with SLE participated in combined concept elicitation/cognitive debriefing interviews, after which the LSQ was revised.

Results: Fourteen patients completed concept elicitation interviews: 93% were female, 57% were white, and 85% had moderate/severe SLE. Current treatments included hydroxychloroquine (93%), steroids (79%), and belimumab (57%), and 43% were biologic naive. Patients were generally satisfied with their treatment and medical care; however, they were dissatisfied with treatment adverse effects and the number of available treatment options. Cognitive debriefing interviews (n = 8) demonstrated that the LSQ was comprehensive, clear, and relevant; therefore, only minor revisions were made to the questionnaire. The LSQ assesses satisfaction with current SLE treatments (25 items), medical care (11 items), and insurance coverage (3 items). The draft LSQ was evaluated in 195 adults with SLE. Fifty-eight percent of patients reported that they were "somewhat satisfied" with their SLE treatment.

Conclusions: The LSQ has been developed to assess treatment satisfaction among patients with SLE. Following further testing to support its validity and reliability, it will provide a useful tool to facilitate assessment of satisfaction with treatments for SLE and help inform treatment decisions.

Key Words: patient satisfaction, questionnaire design, systemic lupus erythematosus

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Systemic lupus erythematosus (SLE) is a chronic disease characterized by a wide range of clinical manifestations and fluctuating symptoms. Several classes of drugs, including glucocorticoids (referred to throughout as steroids), antimalarials, immunosuppressants, biologics, and nonsteroidal anti-inflammatory drugs, have been demonstrated to provide clinical benefit for patients with SLE, but are also associated with adverse effects.[1]

Treatment noncompliance and nonadherence are common problems in chronic conditions,[2] such as SLE; only approximately 25% of patients with SLE take 80% of their prescribed medications or greater over a 2-year period.[3] Nonadherence is associated with worse disease outcomes[4,5] and higher levels of health care resource utilization.[6] Many factors contribute to adherence[7] and satisfaction with treatment,[7,8] including number of medications,[3] regimen complexity,[8] and the balance between treatment efficacy and adverse effects.[7]

Tools to accurately assess treatment satisfaction may provide useful information in both clinical practice, when considering patients' treatment options, and in clinical studies, when evaluating novel treatments. Although generic measures of treatment satisfaction, such as the Treatment Satisfaction Questionnaire for Medication[9] and Treatment Satisfaction with Medicines Questionnaire,[10] have been developed, we have been unable to identify any existing measure that is specific for patients with SLE. While general satisfaction has been assessed in SLE populations,[11–13] these generic satisfaction surveys do not explore the many facets of SLE that are likely to drive patient satisfaction. SLE disease management is unique, given the array of organ manifestations and the varied treatment options available to control these symptoms. Coupled with the fact that few new SLE treatment options have been approved in the past decade and that SLE is often a debilitating and progressive disease, an SLE-specific tool to assess satisfaction with treatment, treatment options, and medical care provides a useful addition to SLE patient satisfaction research.

The aim of this study was to develop a comprehensive, SLE-specific, patient-reported outcome (PRO) measure to assess patient satisfaction with treatment, treatment options, and medical care.

MATERIALS AND METHODS

Study Design and Population

This study (HO13-13424) was designed according to best practices for the development of PRO measures.[14,15] Independent review board approval (Copernicus Group, Durham, NC) was obtained.

Patients were recruited from 4 US rheumatology practices (St Clair Shores, MI; Arlington, VA; Towson, MD; and Lansing, MI). Physicians were required to be rheumatologists currently treating 5 or more patients with SLE. Patients were eligible for inclusion if they were US residents, 18 to 75 years of age, and able to speak and read English; had a clinical diagnosis of SLE; had a Safety of Estrogens in Lupus Erythematosus National Assessment–Systemic Lupus Erythematosus Disease Activity Index score of 4 or greater or had SLE rated as moderate or severe (based on investigator opinion); were receiving belimumab or were naive to biological therapy; and provided written informed consent at the clinic, prior to participating in telephone interviews. Patients

with a medical or psychiatric condition (including lupus-related conditions) or who were receiving treatment for a condition that results in cognitive or other (visual, hearing) impairment that in the investigator's opinion would interfere with participating in the study were excluded. The patient sample had a range of disease severity, race/ethnicity, and organ involvement. The aim was to recruit approximately 50% of patients receiving belimumab and 50% naive to biological therapy, in order to elicit concepts of satisfaction (or dissatisfaction) relevant to both traditional and more recently introduced treatment approaches.

Study sites and participants were remunerated fair market value for their participation.

Questionnaire Development

Each clinical site completed a case report form for each patient, to record the date of diagnosis, SLE severity (as determined by the physician), the presence of comorbid conditions, and use of concomitant medications.

All patient interviews were conducted via telephone and lasted approximately 60 minutes. The first cohort of patients (n = 6) participated in concept elicitation interviews only, which were conducted using a semi-structured interview guide developed specifically for this study. Patients were asked open-ended questions to identify important concepts regarding satisfaction with treatment and medical care. Questions focused on the patients' current treatment (including perceived effectiveness, satisfaction with frequency and mode of administration, adverse effects, and adherence) and their opinion of the health care they receive. A draft of the Lupus Satisfaction Questionnaire (LSQ) was developed based on results from these initial concept elicitation interviews and clinical input; where possible, wording provided by the patients was used.

Subsequent interviews (n = 8) involved concept elicitation and cognitive debriefing of the draft LSQ. In most cases, the concept elicitation interview was conducted prior to the patient completing the draft LSQ. Because of the length of the interviews, not all questions were asked of all patients; therefore, the number of responses provided varies and is stated throughout the results. The items perceived to be the most challenging were specifically queried, and to avoid the interviews becoming overly tedious, patients were not asked to evaluate questions that were very similar to one another. After each round of cognitive debriefing interviews, the responses were reviewed and the draft LSQ was modified accordingly. The revised draft was then used in the next round of interviews. Following the final cognitive debriefing interview, the LSQ was reviewed and refined, with input from clinicians.

Safety was not assessed in the study; however, if a patient reported a potential adverse event during his/her interview, it was reported to the study sponsor, GlaxoSmithKline.

Data Analyses

All interviews were recorded and transcribed for analysis. Patient-identifiable information was removed to ensure patient confidentiality.

Interview data were coded using the qualitative data analysis software MAXQDA (Verbi GmBH, Berlin, Germany). A coding dictionary was developed in order to organize and categorize concepts of interest. To ensure consistency, all transcripts were coded by 1 coder and then reviewed, summarized, and analyzed by a second coder.

Preliminary Evaluation of the LSQ

To conduct a preliminary evaluation of the draft version of the LSQ, it was included as part of a larger survey carried out in the United States in patients with SLE. Patients were required to have a diagnosis of SLE and be older than 18 years; patients were excluded if they worked for or had a close family member who worked for a market research or pharmaceutical company.

RESULTS

Study Population

A total of 14 patients participated in the study; the majority were female (93%, 13/14), 57% (8/14) were white, and 29% (4/14) were African American (Table 1). Few patients (14%, 2/14) had professional/advanced degrees, the majority (57%, 8/14) had an annual income of less than $75,000, and one-third of patients (29%, 4/14) were working full time for pay. According to physician assessment 64% (9/14) of the patients had moderate disease, and 21% (3/14) had severe SLE. The mean time since SLE diagnosis was 10.4 (SD, 10.8) years. Based on patient responses, the most common treatments received by patients were hydroxychloroquine (93%, 13/14), steroids 93% (13/14), and belimumab (50%, 7/14). The mean treatment durations for each of these medications were 6.1 (SD, 6.7), 5.5 (SD, 7.3), and 1.8 (SD, 0.8) years, respectively.

Concept Elicitation Interviews

Patients (n = 9) rated overall satisfaction with their SLE treatment from 0 (not at all satisfied) to 10 (extremely satisfied); the mean overall treatment satisfaction score was 8.7 (range, 6–10). For individual SLE treatments, the mean scores were as follows: prednisone (n = 9), 7.9 (range, 7–10); hydroxychloroquine (n = 3), 7.0 (range, 5–10); and belimumab (n = 3), 9.3 (range, 8–10). When asked about the best and worst aspects of their treatment, the majority of patients remarked on factors relating to the effectiveness and adverse effects of the drugs, respectively (Table 2). When specifically asked about the effectiveness of their treatment, all patients receiving belimumab (100%, 7/7) and the majority of patients receiving steroids (85%, 11/13) and hydroxychloroquine (69%, 9/13) reported that their treatment was effective. Treatment adverse effects were common; 43% (3/7) of the patients receiving belimumab and all (11/11) patients receiving steroids reported experiencing adverse effects at some point, although 45% (5/11) of the patients stated that they were not currently experiencing adverse effects due to steroids. Most patients (92%, 12/13) reported no adverse effects from hydroxychloroquine, and 1 patient was unsure if she experienced adverse effects from hydroxychloroquine (Table 2).

All patients (n = 14) were asked if they found the frequency of administration of their medications to be acceptable. The majority of patients were receiving 1 or more medications once (n = 11) or twice (n = 7) per day or monthly (n = 7). In general, patients found the dose to be acceptable (91% for once per day [10/11], 86% for twice per day [6/7], and 100% for monthly [7/7]). (Note: Subjects could have been on more than 1 medication and responded for each medication.) However, differences were seen regarding mode of administration; compared with patients who received tablets/capsules (7%, 1/14) or an injection (0/2), a larger proportion of patients who received treatment (belimumab) by intravenous infusion reported that it was difficult (50%, 3/6). The main reasons for this were that it is inconvenient because of the need to travel to the clinic and because of the time required for the infusion.

With regard to adherence, 71% (10/14) of the patients reported that they had missed treatments; 2 patients stated that they had intentionally done so (1 patient because she was pregnant and did not think it was needed and 1 patient because she thought it

TABLE 1. Demographics and Clinical Characteristics of All Patients Who Completed a Concept Elicitation Interview

Characteristic		Subjects (N = 14)
Gender, n (%)		
Male		1 (7)
Female		13 (93)
Mean age (SD) (range), y		41.6 (11.7) (19–61)
Ethnicity, n (%)		
White		8 (57)
African American		4 (29)
Latino/Hispanic		1 (7)
Other		1 (7)
Education, n (%)		
Some college		7 (50)
College degree		5 (36)
Professional/advanced degree		2 (14)
Annual income, n (%)		
<$25,000		4 (29)
$25,000–$49,999		1 (7)
$50,000–$74,999		3 (21)
$75,000–$99,999		2 (14)
>$100,000		2 (14)
Not provided		2 (14)
Employment status,[a] n (%)		
Not currently working for pay outside home		2 (14)
Working full time		4 (29)
Working part time		0
Retired		1 (7)
Student		1 (7)
Disabled		7 (50)
Mean time since SLE diagnosis (SD) (range), y		10.4 (10.8) (1–39)
SLE severity, n (%)		
Mild		2 (14)
Moderate		9 (64)
Severe		3 (21)
Current SLE treatment[b,c]	n (%)	Time on Treatment, Mean (SD) (range), y
Hydroxychloroquine	13 (93)	6.1 (6.7) (1–24)
Steroids	13 (93)	5.5 (7.3) (<1–24)
Belimumab[d]	8 (57)	1.8 (0.8) (<1–3)
Methotrexate	4 (29)	2.2 (0.8) (1–3)
NSAIDs	2 (14)	1.5 (0.7) (1–2)
Azathioprine	1 (7)	0.08
Concomitant condition, n (%)		
Fibromyalgia		7 (50)
Hypertension		4 (29)
Depression		3 (21)
Osteopenia/osteoporosis		3 (21)
Hyperlipidemia/hypercholesterolemia		2 (14)
Osteoarthritis		2 (14)
Rheumatoid arthritis		2 (14)
Vasculitis		2 (14)
Lupus nephritis		2 (14)
Asthma		1 (7)
Diabetes		1 (7)
Sjögren's syndrome		1 (7)
Antiphospholipid syndrome		1 (7)

TABLE 1. *(Continued)*

Characteristic	Subjects (N = 14)
Deep vein thrombosis	1 (7)
Pulmonary embolism	1 (7)
Chronic kidney disease	1 (7)
Raynaud's phenomenon	1 (7)
Mixed connective tissue disease	1 (7)

Because of rounding, totals may not equal 100%.

[a]One patient selected "full-time" and "student."

[b]Patients may have been receiving more than 1 treatment.

[c]Based on data from the CRFs, patient self-reported current treatment differed: 7 patients reported receiving belimumab, 4 reported receiving mycophenolate mofetil, and no patients reported the use of NSAIDs or warfarin.

[d]One patient had discontinued belimumab 6 months prior to the study.

CRF indicates case report form; NSAIDs, nonsteroidal anti-inflammatory drugs.

was not working), and 9 patients unintentionally missed a dose (9 patients because of forgetting, and 1 patient also ran out of tablets). In addition, 56% (5/9) of the patients reported that they sometimes take their medications later in the day than prescribed.

Patients reported some dissatisfaction regarding the number of treatments available for SLE; 64% (9/14) said that there were not enough treatments available, 29% (4/14) thought that there were enough, and 7% (1/14) were uncertain. The dissatisfaction is exemplified by 1 patient who responded, "…lupus doesn't get the attention like other areas. It's getting better because nobody even knew what the word was when I was diagnosed. It's becoming, they're more aware of it now. To have only 1 drug breakthrough in 50 years to be added to the list to treat it, no, I don't think there's enough. I think that there should have been more that they can do for that by now."

Patients were also questioned regarding their opinion of their medical care. The majority of patients were happy with their relationships with their rheumatologist and nurses and how decisions about their treatment are made (Table 3). Patients also reported a high degree of satisfaction with the ease of getting an appointment with their rheumatologist and the amount of time spent for each consultation.

Questionnaire Development and Cognitive Debriefing Interviews

An initial draft of the LSQ was developed based on the concepts identified during the first 6 concept elicitation interviews. Some revisions were then made based on clinician input. For example, the recall period was changed from 1 month to 3 months because 1 month was thought to be too short a period to assess a new treatment. Questions relating to satisfaction with health insurance, an aspect not discussed in the concept elicitation interviews, were also added based on the clinical feedback. The resulting draft of the LSQ contained 15 items assessing satisfaction with current lupus treatments, 11 items assessing satisfaction with health care providers, and 3 items assessing satisfaction with insurance coverage for lupus treatments. For the majority of questions, the response options ranged from 1 (very dissatisfied) to 7 (very satisfied).

A second patient group (n = 8) participated in a combined concept elicitation interview and cognitive debriefing of the draft LSQ. Mean age was 42.6 (11.58) years, 88% (7/8) were female, 53% (5/8) were white, 25% (2/8) were African American, 25% (2/8) had severe disease and 75% (6/8) had moderate disease. All patients had received hydroxychloroquine, 88% (7/8)

had received steroids, and 53% (5/8) had received belimumab. Most patients (86%, 6/7) took approximately 5 minutes to complete the LSQ; 1 patient took approximately 10 minutes. Most patients (88%, 7/8) found it easy to respond to all questions and thought the response options were appropriate. One patient suggested revising the questions regarding treatment satisfaction so that the questions were asked separately about tablets/capsules, injections, and infusions. This revision was incorporated following the seventh cognitive debriefing interview, and the revised draft was debriefed in the final interview. During this final cognitive debriefing interview, there was little new information provided.

The majority of patients (75%, 6/8) thought the 3-month recall period was appropriate, 1 patient would have preferred a longer period (6 months), and 1 patient would have preferred a recall period of 2 weeks. While some patients said they would have answered the same if the recall period had been 1 month (86%, 6/7) or 1 year (43%, 3/7), the 3-month recall period was retained because it was endorsed by the majority of patients (75%, 6/8) and recommended by clinicians as being an appropriate period over which to assess a new treatment.

Except for the change described above, only minor revisions were made to the wording of some questions to improve clarity. For example, "different" was added to the question, "In the past 3 months, how satisfied or dissatisfied were you with how well your different health care providers worked together to treat your lupus?" to clarify that it is referring to the full team of health care providers.

The revised LSQ contains 39 items (Table 4) and asks patients to consider all SLE treatments they have received in the past 3 months.

Preliminary Evaluation of the LSQ

As a preliminarily evaluation of the LSQ, a draft version was included in a survey carried out in the United States. Of the 195 patients, 73% were female, mean age was 41.7 years, mean time since SLE diagnosis was 10.5 years, 41% were employed full time, and 53% had children. In this survey, 58% of patients reported that they were at least "somewhat satisfied" with their SLE treatment. Patients who reported a lower frequency of adverse effects and who experienced more "good days" than "bad days" were more likely to report that they were satisfied. The majority (85%) of the patients stated that they were "completely," "very," or "moderately" satisfied with their clinician's management of their SLE, and 63% of patients were at least "somewhat satisfied" with the amount of time spent with their health care provider

TABLE 2. Treatment Satisfaction: Responses From Concept Elicitation Interviews

What Are the Best Things About the Treatment?[a]

Treatment	Most Common Responses, n (%)	Representative Quotes
Belimumab (n = 7)	Lessens the pain, 3 (43) Results in more energy, 3 (43) Lessens swelling, 2 (29) Clears the "mind-fog", 2 (29) Has no adverse effects, 2 (29)	"I would say within the first 2 weeks it was like I got my energy of 15 years that I never had before. It was like my wonder drug."
Steroids (n = 11)	Reduces pain and stiffness, 7 (64) Results in more energy, 4 (36) Controls flares, 3 (27)	"It reduces my soreness and my stiffness just immediately."
Hydroxychloroquine (n = 12)	Effective, 5 (42) No adverse effects, 4 (33) Minimizes flares, 2 (17) Nothing, 3 (25)	"Probably the best thing is that it probably helps with more stuff that I can't actually physically notice, like the stuff that's stopping my body from fully attacking itself."

What Are the Worst Things About the Treatment?[a]

Treatment	Most Common Responses, n	Representative Quotes
Belimumab (n = 6)	Nothing, 2 (33) Inconvenience of administration, 2 (33) Feeling tired immediately after the infusion, 1 (17) Being prone to infections, 1 (17) Expense of the treatment, 1 (17)	"I guess maybe the worst is the time that, you have to go in every month for the hour, hour and a half, but honestly I really haven't experienced anything that I would consider the worst…" "Worst thing is the day I receive it also, you can almost, by the time you leave the doctor's office you can feel; I've talked to other patients there about it too, and you can barely make it home; it makes you so tired. I mean you have to drive home after because you have to receive it at the doctor's office…"
Steroids (n = 10)	Long-term adverse effects, 6 (60) Weight gain, 4 (40) Insomnia/agitation, 2 (20)	"I guess it's a long-term effect that it can have on you. Right now I haven't had any negative effects, but my doctors keep telling me that if I stay on it for long periods of time, I could get osteoporosis and make my bones really weak and everything."
Hydroxychloroquine (n = 11)	Nothing, 4 (36%) Long-term adverse effects, 2 (18) Need to take it for the rest of their life, 2 (18)	"The worst thing is knowing that I will be probably on it the rest of my life, will not be able to stop it, take a break from it, that's probably the worst thing because I can't take a break from it."

Treatment Effectiveness[a]

Treatment	Effectiveness, n (%)	Change in Effectiveness Over Time, n (%)	Representative Quotes
Belimumab (n = 7)	Effective, 7 (100)	More effective, 3 (43) No change, 3 (43) Less effective, 1 (14)	"Prior to the, me having problems with my lungs, it was working well, and I can tell because every time it would be close to time for me to get another infusion, I would start to feel bad."
Steroids (effectiveness, n = 12; effectiveness over time, n = 8)	Effective, 10 (83) Partially effective, 1 (8) Not effective, 1 (8)	No change, 6 (75) Variable, sometimes more and sometimes less effective, 1 (13) Less effective, 1 (13)	"Prednisone works great; I wish I could be on a high dosage on it all the time. When I'm on prednisone, everything is fine."
Hydroxychloroquine (effectiveness, n = 13; effectiveness over time, n = 12)	Effective, 9 (69) Not effective, 1 (8) Don't know, 3 (23)	More effective, 2 (17) No change, 9 (75) Less effective during times of stress, 1 (8)	"Actually I think it's working very well. Because I don't have the pain that I used to. I don't have, I'm not as tired as I once was."

TABLE 2. *(Continued)*

Treatment Adverse Effects[a]

	Reported Adverse Effect, n (%)	Representative Quotes
Belimumab (n = 7)	Feeling tired, 2 (29) Headaches, 1 (14) Pain in the arm following infusion, 1 (14) Feeling achy, 1 (14) Heaviness in the arm, 1 (14) None, 4 (57%)	"I had migraines, a severe migraine to the point where you're laying with a washcloth over your eyes because you just, it just hurts so bad." "I wouldn't say anything at all bad about Benlysta."
Steroids (n = 11)	Weight gain, 6 (55) Swelling or moon face, 5 (45) Bone loss/osteoporosis, 3 (27) None, 5 (45)	"It just causes more issues with my system. It makes it go in chaos. I get more wired up. It's bad enough I don't sleep as it is, then I really can't sleep."
Hydroxychloroquine (n = 13)	None, 12 (92) Don't know, 1 (8)	"I haven't had any issues with that I know of, but I'm on so many medications I don't know what a reaction would be with Plaquenil (hydroxychloroquine), so I can't really say because of all the medications that I'm on."

[a]Patients were questioned regarding current and previous treatment and were permitted to provide more than 1 answer.

TABLE 3. Satisfaction With Health Care

Factor	Response, n	Representative Quotes
Relationship with rheumatologist (n = 14)	Very satisfied, 11 Satisfied, 2 Somewhat satisfied, 1	"I think we have a good relationship, an honest relationship. I can pretty much discuss anything and everything with them in that, and if there is an issue that I'm having with something else, they have no problem forwarding my notes or whatever to that doctor or discussing it with the doctor. So I think we have a pretty good relationship."
Relationship with nurse (n = 9)	Very good or good, 8 Civil, 1	"They've always been very kind and courteous, and as a matter of fact, I think they're so young and green that they don't have time to develop; you know they're so eager to please that it's not like somebody that's probably been in the same position for 20 years and is kind of a little humdrum about things."
Duration of consultation with rheumatologist (n = 14)	Sufficient, 13 Not sufficient, 1	"Because he's not rushed even if he has a lot of patients, and he does see a lot of patients in the day, but if you have a question, he's there to answer it."
How treatment decisions are made (n = 14)	Happy, 13 Unhappy, 1	"Collectively. Me, my rheumatologist, and my primary care. That's a must for me that we are all on the same page." "He kind of gives me suggestions about certain treatment options if I feel like what I have currently been doing is not working, and then he basically gives me 3 minutes to decide, and then that's what it is, very little time for me to think it over, research anything, and discuss it with my husband, with our insurance policy."
Ease of getting an appointment with their rheumatologist (n = 14)	Easy, 13 Difficult, 1	"It's not difficult, but I think it might be because I'm a well-established patient. You know if I called and said I am having a definite problem, can I get in, they will fit me in either that day or the next day."
Ease of contacting their nurse or doctor outside their regular appointment time (n = 12)	Easy, 11 Difficult, 1	"I call the doctor's office all the time. I typically get a great response. I get an even better response through the e-mail system that we have."

TABLE 4. Summary of Items Included in the LSQ

Questions	Items	Sample Items
1–4	Effectiveness	Over the past 3 months, how satisfied or dissatisfied were you with how well your treatment controlled your lupus symptoms?
5–6	Adverse effects	Over the past 3 months, how satisfied or dissatisfied were you with the short-term side effects of your treatment?
7–11	Treatment administration (Tablets/capsules)	Over the past 3 months, how satisfied or dissatisfied were you with how convenient it was to receive your treatment?
12–16	Injections	Over the past 3 months, how satisfied or dissatisfied were you with how frequently you needed to receive your treatment?
17–21	Intravenous drip	Over the past 3 months, how satisfied or dissatisfied were you with how frequently you needed to take time away from work or your other usual activities to receive your treatment?
22–25	Overall satisfaction	How willing or unwilling would you be to recommend your current treatment to someone else with lupus?
26–36	Satisfaction with health care providers	Over the past 3 months, how satisfied or dissatisfied were you with how easy it was to get an appointment at a time that was convenient for you?
37–39	Health insurance aspects	Over the past 3 months, how satisfied or dissatisfied were you with the amount of time it took to obtain approval from your health care plan/insurance provider to cover your lupus treatment?

during a consultation. This initial data from the draft LSQ provide some verification of the appropriateness of the items and response options given in the measure, as patients generally provided a range of responses, and very few answered "didn't know" or "not applicable." As this was a cross-sectional survey, it was not possible to follow up with patients to explore responses on the LSQ in greater depth.

DISCUSSION

To the best of our knowledge, the LSQ is the first comprehensive PRO measure designed for use patients with SLE, to specifically assess satisfaction with treatment, treatment options, and medical care. The PRO was developed according to best practices and as such, used significant patient input, an iterative development process, clinical input, and cognitive debriefing of the draft questionnaire.[14,15] The resulting draft of the questionnaire contains 39 items that assess treatment effectiveness, adverse effects, administration, overall treatment satisfaction, and satisfaction with health care providers and insurance. Patients are asked to consider all SLE treatments received in the last 3 months; therefore, it is important to obtain the comprehensive treatment history.

Patient input is critical to the development of PROs to ensure that all relevant concepts are identified and that the PRO is developed from the patient perspective.[14,15] Although the sample size was relatively small in this study, it was demographically broad in terms of age, ethnicity, and geographic location. Although only 1 of the 14 patients was male, SLE affects more females than males (ratio of 9:1),[16] such that the 13:1 ratio in the current sample seems appropriate. In addition, the majority of patients were white (57%), just under a third were African American (29%), and 7% were Hispanic. However, the LSQ will be further evaluated in a larger, more representative patient population. While the sample size in this study was small, and not all items were reviewed by all patients, we are confident that the sample size was sufficient to identify all important concepts and to confirm the content, clarity, and relevance of the PRO. Many items were conceptually similar to those reviewed by patients, and patient feedback resulted in

very few, minor revisions to the questionnaire. By the last interview, there was little new information provided.

Patients should preferably not participate in both concept elicitation and cognitive debriefing interviews, whereas in this study the second cohort completed combined concept elicitation and cognitive debriefing interviews. To avoid bias, in most cases, the concept elicitation interview was performed before the patient completed the questionnaire; however, separate interviews may have enabled more detailed exploration of concepts and questionnaire feedback. Therefore, subsequent evaluation of the measure will explore whether the concepts captured in the LSQ are sufficient. Another limitation of the study was that all interviews were conducted via telephone. Although this enabled the study to be conducted over a wide geographic location, face-to-face interviews allow the interviewer to respond to any confusion suggested by patients' facial expressions and/or body language.

Preliminary evaluation of the LSQ suggests that the items and responses are appropriate. Future validation including conducting factor analysis and evaluating internal consistency reliability, test-retest reliability, construct validity, and known group validity should be performed. To evaluate test-retest reliability, it will be necessary for a subgroup of stable patients to complete the questionnaire 7 to 10 days after their initial response. Furthermore, to enable longitudinal use of the questionnaire, a cohort will need to complete the questionnaire twice, approximately 3 months apart, so that responsiveness, sensitivity over time, the minimum clinically important change, and responder definition can be assessed. Following demonstration of these measurement properties, the LSQ will be a useful measure in clinical studies and clinical practice. In naturalistic studies, the LSQ may provide important information to fully evaluate satisfaction with novel treatments. In clinical practice, the LSQ should enhance the dialogue between physicians and patients about factors that drive satisfaction with SLE treatment. Enhanced dialogue may help align patient and clinician priorities and needs regarding treatment and may prove useful in future treatment decisions. It is of note that the concept elicitation interviews found that patients have a relatively high level of satisfaction with their treatment despite reporting high levels of adverse effects, suggesting that patients have a low level of expectation regarding the

treatment of SLE. As new treatments become available, the LSQ may provide a useful tool to monitor changes in treatment expectations and satisfaction.

In summary, data from concept elicitation and cognitive debriefing interviews and clinical input were utilized to develop the LSQ, a questionnaire designed to assess patient satisfaction with SLE treatment, treatment options, and medical care. Further validation and evaluation are required to support its future use in SLE clinical trials and clinical practice.

KEY POINTS

- The Lupus Satisfaction Questionnaire (LSQ) is a comprehensive patient-reported outcome (PRO) measure designed to specifically assess satisfaction with treatment, treatment options, and medical care in systemic lupus erythematosus.
- This PRO was developed according to best practices, using an iterative development process with significant input from patients and clinicians.
- The LSQ contains 39 items that assess treatment effectiveness, adverse effects, administration, overall treatment satisfaction, and satisfaction with health care providers and insurance.
- Preliminary evaluation of the draft LSQ suggests that the items and response options are appropriate, as patients provided a range of responses and very few selected "didn't know" or "not applicable."

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