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Development of the American College of Rheumatology's Patient-reported Outcome Quality Measures for Systemic Lupus Erythematosus

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Abstract

Background: As part of a Centers for Disease Control and Prevention-funded ACR initiative, we sought to develop quality measures related to Patient Reported Outcome Measure (PROM) use for SLE clinical care.

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Methods: An expert workgroup composed of physician, patient, and researcher representatives convened to identify PRO domains of greatest importance to people with SLE. A patient advisory panel separately ranked domains. PROMs assessing priority domains were identified through structured literature review and detailed psychometric reviews were conducted for each PROM. In a Delphi process, the expert workgroup rated PROMs on content validity, psychometric quality, feasibility of implementation, and importance for guiding patient-self management. The patient advisory panel reviewed PROMs in parallel and contributed to the final recommendations.

Results: Among relevant PRO domains, the workgroup and patient partners ranked depression, physical function, pain, cognition, and fatigue as high-priority domains. The workgroup recommended at least once yearly measurement for 1) assessment of depression using the Patient Health Questionnaire or Patient Reported Outcomes Measurement Information System (PROMIS) depression scales; 2) assessment of physical function using PROMIS physical function scales or the Multi-Dimensional Health Assessment Questionnaire (MDHAQ); and 3) optional assessments of fatigue and cognition. Pain scales evaluated were not found to be sufficiently superior to what is already assessed in most SLE clinic visits.

Conclusions: Expert workgroup members and patient partners recommend that clinicians assess depression and physical function at least once yearly in all people with SLE. Additional PROMs addressing cognition and fatigue can also be assessed. Next steps are to incorporate PROM-based quality measures into the ACR's RISE registry.

Background

Systemic lupus erythematosus (SLE) is a complex and heterogeneous chronic autoimmune disease that can affect multiple organ systems and cause a wide range of symptoms in a given patient.[1–3] Despite significant progress in the pharmacological management of SLE,[4] there remains a need to understand and address the patient experience of illness more fully, particularly as there is often discordance between physician and patient assessments of disease.[4–8] One important strategy for gaining this understanding is using standardized patient-reported outcomes (PROs). PROs can provide valuable insights into the impact of the disease on overall well-being, functioning, and physical and mental health.[9–11] Additionally, PROs can aid shared decision-making and help patients and physicians understand the impact of pharmacological and non-pharmacological treatments on health-related quality of life (HRQoL).[12–15] However, while Mosca et al recommended evaluating quality of life for patients with SLE as part of the EULAR Quality Indicators in 2011[16], these recommendations have not been widely implemented, and no updated or specific recommendations exist for PRO use in SLE clinical care.

Numerous studies utilizing a variety of research designs have been conducted to evaluate PROs in SLE. These studies have revealed that multiple domains of quality of life can be affected, including physical function, mood, cognition, fatigue, pain, and work-related abilities, among others. Studies have also shown that SLE can have a similar or even greater impact on HRQoL compared to other chronic conditions, with HRQoL often being lower in individuals with SLE than in those with rheumatoid arthritis or type 2 diabetes.[17–21] The quality of life and physical functioning of individuals with SLE can be severely impacted, with factors such as fatigue, pain, and joint dysfunction contributing to this decline.[22–24]

Additionally, levels of depression and anxiety are often high (35%) among individuals with SLE.[25–28] As a result, developing a comprehensive care plan for individuals with SLE often requires attention to HRQoL domains assessed with PROs.

In collaboration with the Centers for Disease Control (CDC), the American College of Rheumatology (ACR), and patient partners, we aimed to develop PRO-based quality measures for routine clinical monitoring in SLE. To arrive at recommended measures, we reviewed formative articles identifying HRQoL domains that people with SLE consider important, identified specific instruments to measure these prioritized outcomes after considering their psychometric properties and feasibility for routine clinical use, and conducted Delphi consensus procedures to arrive at the final measures. This work contributes to the larger suite of measures the ACR has developed for monitoring and improving the quality of care for people with rheumatic diseases.[29–33]

Methods

The project took place in four phases: Phase 1 focused on PRO domain identification and review, Phase 2 on identifying and reviewing PRO instruments within domains, Phase 3 on feasibility and psychometric assessments, and Phase 4 on selecting and prioritizing recommended PROs and defining PRO-based quality measures (Figure 1).

Participants

Two panels participated in the project: A) an expert workgroup composed of 10 physicians and researchers with expertise in SLE clinical care, SLE clinical research, and/or PRO assessment in SLE, plus a patient representative, and B) an advisory panel of 11 patient partners. Patient partners were identified through clinics and patient advocacy organizations. Ten of the 11 patient partners were female. They represented a range of ages (18–30 years, 1; 31–40 years, 4; 41–50 years, 4; 51–60, 1; and 60+, 1) and geographic locations (California, 6; Florida, 1; Georgia, 1; Massachusetts, 1; New York, 1; and North Carolina, 1). Eight patient partners self-identified as Black, two Asian, and one White; two self-identified as Hispanic/Latina. Four had a history of lupus nephritis. Patient advisory panel meetings were conducted a 60-minute expert-facilitated focus groups. All panel meetings were conducted virtually. Five meetings were held. The first focused on an introduction to the project and the remaining four were focused on a single phase of work, as described below. Three Patient Advisory Group members attended all five meetings, two attended four, and three attended three. Importantly, eight of the eleven attended the final meeting in which measures were reviewed and voted on for endorsement.

Phase 1: PRO domain identification and review

Expert Workgroup—One expert workgroup member (CEHB) conducted a structured literature search. The search focused on papers that reported the patient's perspective on important patient-reported domains, including the formative literature for developing SLE-specific quality-of-life measures. Literature was limited to the past 20 years to reflect the modern era of treatment and SLE outcomes. Guidance for the qualitative evidence synthesis

was derived from the Cochrane Handbook for Systematic Reviews of Interventions chapter on qualitative evidence.[34]

Four electronic medical databases (MEDLINE, EMBASE, Psychinfo, and CINHAL) were searched using specified MeSH terms and keywords (See Supplemental Table 1). Reference lists of existing studies were manually searched to identify potentially relevant additional studies, and content experts were contacted to review results and ensure the completeness of the search.

Following the systematic search, we used purposive sampling to identify articles most relevant to our overall aim of identifying patient priorities for outcomes. The prespecified inclusion criteria included 1) English language studies published from 2001 to June 2021, and 2) quality of life measure development studies, and 3) studies where outcome prioritization was described using qualitative methods, or 4) qualitative or quantitative studies on the lived experiences of persons with SLE focused on describing their outcomes priorities. Non-English language studies, reviews, commentaries, conference abstracts, COVID-19-specific studies, and studies of pediatric SLE and other rheumatic disease populations were excluded.

Abstracts of all identified studies were screened by a workgroup member (CEHB), and relevant papers underwent a full-text review by at least two other workgroup members. During the review, the following data elements were collected using a pilot-tested data extraction form: subthemes and themes (and select quotations if appropriate for most important themes); any explanations, hypotheses, or new theory from authors on prioritization of patient outcomes; and detailed design and contextual information from the studies including study year, study design, number of participants, recruitment strategy, and participant characteristics (e.g., age, gender, race and ethnicity, education, SLE duration).

Expert workgroup members then used a modified Delphi method to prioritize domains. Workgroup members reviewed findings from the literature, independently ranked the domains, met to discuss preliminary rankings, reviewed relevant literature, and then submitted a final ranking. This process resulted in a ranked list of domains that the workgroup found most important for assessment in the clinical setting to improve outcomes.

Patient Advisory Group—Patient partners participated in a focus group where they were asked to identify the disease-related symptoms that mattered to them the most and what types of PROs they would like their rheumatologist to track over time. Patients performed ranking exercises in an anonymous follow-up poll to prioritize the PRO domains.

Phase 2: Identification and review of PRO instruments within prioritized domains

Expert Workgroup—To identify PRO instruments for each domain, the special issue summary from *Arthritis Care & Research* on outcomes measures in rheumatology, published in October 2020, was first examined along with other systematic and expert reviews on PROs in Lupus.[10,11] Additional PROs were added based on expert review and targeted literature search of the prioritized domains. Both generic and SLE-specific quality-of-life

measures were included if they included items or subscales that addressed the domains identified and prioritized in the project's first phase.

Initial screening of each measure was conducted to identify the number of survey items, whether the scale had previously been used among individuals with SLE, whether fees were required, and whether the measure was available in languages other than English. The workgroup used this information to decide which measures to retain for a full psychometric review. Measures that had not been or were uncommonly used in SLE in the past ten years, had not been used among US SLE patients, that required fees, were not available in English and Spanish at a minimum, were primarily appropriate for other conditions, or that had visual components (e.g., visual analog scales) that might be difficult to implement in digital applications were excluded from further consideration.

Phase 3: Feasibility and psychometric assessments

Expert Workgroup—Psychometric reviews were conducted on the retained PRO instruments by a research assistant (NSH) under the direct supervision of a workgroup member (CEHB). The psychometric review used a structured process, collecting information on reliability, content validity, other validity, floor and ceiling effects, and responsiveness. Reviews also determined whether the psychometric properties had been confirmed in SLE.

Once reviews were completed, two members of the workgroup independently rated the quality of each measure on each component using the following scale: acceptable, not acceptable, inconsistent, or insufficient information to determine acceptability, leveraging methods described by Hendrikx et al.[35] Any differences in opinion were adjudicated and resolved by two reviewers. Psychometric ratings and evaluations and the full instrument were then presented to the workgroup to inform the review and evaluation of feasibility. The workgroup then engaged in a second modified Delphi process (e.g., review of literature summaries, voting, group discussion, followed by a final vote) to rate the following aspects of each measure on a 1 to 9 scale by blind electronic polling: a) how well it captured the symptom (1 = not at all; 9 = very much); b) psychometric quality (1 = poor or unclear psychometric properties; 9 = excellent psychometric properties); c) importance to clinicians in managing SLE (1 = not useful at all; 9 = very useful; d) importance to patients to guide self-management (1 = not useful at all; 9 = very useful); e) feasibility of asking people with SLE to complete the measure during a routine clinical encounter (1 = not feasibility; 9 = very feasible). Using these ratings, the workgroup selected measures for each domain that had the best balance of feasibility, psychometric quality, and provision of important information.

Patient Advisory Group: Patient partners participated in sequential focus groups examining the individual PRO instruments under consideration, including each item in each instrument. Patients discussed each measure in terms of its content and positive and negative aspects, focusing on whether it adequately represented their illness experience. After discussion, participants selected the measures they felt best represented each PRO domain.

Phase 4: Selection of recommended PROs and development of quality measures

Expert Workgroup—The workgroup conducted a modified Delphi exercise to determine the maximum number of domains that should be measured during a clinical encounter, taking into consideration the length of time to complete prioritized measures, feasibility for clinicians in routine clinical settings, and patient burden, and discussed how often measures should be completed. Additional polling was conducted to identify which specific domains should be prioritized for routine measurement given limited time and resources. After reviewing results of the polls, the workgroup reached a consensus on measures to recommend for the quality measure(s) and the wording and specifications of the measures. In the last stage, the workgroup had a final vote and discussion on the feasibility, validity, and meaningful assessment of the quality of care and finalized the frequency with which measures should be completed.

Patient Advisory Group: The patient focus group reviewed the selected measures and voted on the number of PRO domains that should be included in quality measures. They then voted on specific two- and three-measure bundles of measures to recommend. As part of their discussions, patient partners completed examples of these measures bundles so that they could comment on the burden of measurement.

Results

Phase 1: PRO domain identification and review

A total of 3176 articles were identified in the literature search (Supplemental Figure 1). Removal of duplicates resulted in 2505 remaining for screening. After screening, 46 articles were retained for full-text review. Four articles were added by expert recommendation, yielding 50 articles included in the structured domain identification review (Supplemental Table 2). After full-text review, 25 articles were removed because they did not include domain identification.

In the remaining 25 articles, twelve domains were identified in ≥25% of the papers (Table 1). Fatigue was mentioned in all 25 articles, and pain in all but 1. Function, emotional or mental health, and productivity were mentioned in 80% of the articles. Other domains identified in at least 50% of the articles were social well-being, skin issues (e.g., rashes), body image, and cognition. Nine domains were considered generic (e.g., physical function), while three were more SLE-specific (skin issues, body image, and reproductive issues).

After reviewing the domain search results, the expert workgroup ranked domains on their importance to assess during routine clinical care. Fatigue was ranked the highest, followed by pain, mental health, physical function, and cognition (Table 2).

Patients identified similar disease-related symptoms that mattered the most: pain, physical function, fatigue, cognitive symptoms such as brain fog, depression and anxiety, social functioning, and quality of life. Initial median ratings by the patient group for personal importance of all domains was ≥8 on a scale of 1 (not important) to 9 (greatest importance). Patients' initial median ratings of the importance for their doctor to track were 9 for all except for anxiety and social function. In the follow-up poll, patients ranked domains

the same five domains received the highest rankings as in the expert workgroup ratings, although the order was slightly different (Table 2). The expert workgroup and the patient advisory panel agreed to move to the next steps focusing on these top five domains: fatigue, pain, mental health, physical function, and cognition.

Phase 2: Identification and review of PRO measures within domains

Forty-one PROs were mapped to the five domains. An additional five generic quality-of-life PROMs and three SLE-specific quality-of-life PROMs were added to the initial review because they included items or subscales measuring the relevant domains, yielding a total of 49 PROMs considered. Twenty-six measures were excluded (Supplemental Table 3), leaving 23 for detailed review.

Phase 3: Feasibility and psychometric assessments

Table 3 shows the median ratings of the expert workgroup of measure attributes. (Supplemental Tables 4 and 5 show the detailed psychometric review and evaluations presented to the workgroup before rating.) Lower ratings on feasibility were most often attributable to a greater number of items in a questionnaire or difficult scoring algorithms. The mixed quality-of-life measures were dropped from further consideration because they had content overlapping with some domain-specific measures (e.g., physical function), and most had too many items to be feasible for routine clinical use. The workgroup focused on short forms for domains covered by PROMIS measures since online administration via computer-assisted technology might not be universally available. All short-form versions were considered for a given domain.

After discussing the text of each measure, the patient focus group selected preferred surveys for each domain (Table 4). Of note, the patient group felt that the pain measures did not adequately capture either their experiences of pain or the important aspects of pain (e.g., location and quality of pain).

The workgroup selected one preferred measure for each domain based on the feasibility and psychometric assessments and the patient comments and preferences (Table 5).

Phase 4: Selection of recommended PROs and development of measurement strategy

Most of the expert workgroup (67%) felt that two domains should be recommended for assessment in routine clinical care; the remainder chose three domains. When considering two domains, the combination of domains unanimously chosen by the workgroup after reviewing patient feedback was physical function and depression. The third measure chosen was evenly split between fatigue and cognition in a three-measure bundle. Most of the patient advisory group voted for three domains (80%). The most highly rated three-domain bundles included physical function and depression; the additional third measures were pain, fatigue, and cognition (Supplemental Table 6).

Next, after considering patient input, feasibility, and potential for public health impact, the workgroup made a unanimous decision to recommend systematic measurement of two domains, physical function and depression. The decision was also unanimous to include

fatigue and cognition as optional assessment domains. The workgroup opted to exclude the measurement of pain for two reasons: (1) none of the pain measures (e.g., PROMIS Pain Interference, single-item numeric rating of pain severity) resonated with the patient group, and (2) in an examination of the national Rheumatology Informatics System for Effectiveness (RISE) registry[36], the ACR's national electronic health record based registry that includes over 30,000 individuals with SLE, at least 73.5% of SLE patient visits included mention of pain in a structured field. Because of this, the workgroup felt that pain was being adequately assessed in clinical settings and that addition of pain in a quality measure set would not have a substantial public health impact. The patient group endorsed this decision.

Measurement frequency.—The workgroup rated annual administration of both measures as more feasible than measurement at every visit or most visits (Supplemental Table 7). Ratings of face validity as a measure of quality were high and roughly equivalent for both measures (8 out of 9 for physical function and 8.2 out of 9 for depression). Ratings of whether the measurement period was a meaningful assessment of the quality of care slightly favored annual administration (Supplemental Figure 2).

Specification of PRO quality measure concepts.—The expert workgroup and the patient advisory group unanimously agreed upon the two quality measures regarding PRO assessment:

- If a patient has SLE, then physical function should be assessed at least once during the measurement year using an ACR-preferred assessment tool (i.e., any PROMIS physical function scale or the MDHAQ) or other tools deemed acceptable by the ACR.

  Evidence Summary: Physical activity can improve fatigue, depression, and physical fitness and cardiovascular health among patients with SLE.[37]

- If a patient has SLE, then symptoms of depression should be assessed or screened at least once during the measurement year using the ACR-preferred assessment tool (i.e., the Patient Health Questionnaire-8 (PHQ-8)) or other tools deemed acceptable by the ACR.

  Evidence Summary: Depression and anxiety correlate with higher pain, fatigue, and symptom scores and lower medication adherence in patients with SLE;[38] treatment of depression and anxiety improves quality of life.[48–50]

Although the evidence summary includes both anxiety and depression, anxiety was dropped from the quality measure. Both the research literature and patient partner discussions about mental health were highly focused on depression. Patients in particular stressed the importance of this domain, highlighting the high prevalence of depression as well as suicides among people with lupus. Given the decision to include only two measures and the desire to increase feasibility, anxiety was dropped from the quality measure, at least at this initial stage.

Discussion

The present PRO quality measures contribute to the first set of ACR-endorsed SLE quality measures. The quality measures were developed following a literature review coupled with extensive engagement with patients, clinicians, and lupus PRO and quality measurement experts. Two PRO measures were endorsed based on their feasibility, validity, and public health impact: physical function assessment and depression screening, with fatigue and cognitive function assessment representing optional domains for measurement.

While ACR quality measure development processes typically follow standard procedures, including initial measurement concept development based on guideline recommendations, then refinement through an expert panel consensus process,[39] the present method for developing endorsed, PRO-based quality measures was unique and deliberately conducted to maximize patient engagement and incorporate patient priorities. Initial evaluation of the literature for patient-important health domains and ranking priorities between the two panels revealed remarkable alignment between health care professionals and patient partners across the top five priority domains: fatigue, pain, mental health, physical function, and cognition. While SLE-specific instruments exist that address these domains as part of the quality of life[40] or lupus impact;[41] such measure batteries were determined to be less feasible to implement in routine clinical practice or for implementation as quality measures, which often represent a feasible, minimal standard, especially when incorporated into physician payment programs.

Physical function is an important domain that impacts participation in work, family, and leisure activities.[42] PROMIS physical function short form 10A or computer adaptive testing (CAT) versions were preferred given their rigorous development and superior psychometric properties.[8,43,44] The Multidimensional Health Assessment Questionnaire (MDHAQ)[45] is widely used in rheumatology practices across the US, primarily as part of the Routine Assessment of Patient Index Data 3 (RAPID3).[46] Our review with experts and patients deemed this was also feasible and an acceptable instrument, as there was available evidence in SLE.[47] Therefore, if the MDHAQ is already being administered as part of the RAPID3, this is deemed acceptable, even though the PROMIS Physical Function scale has stronger measurement properties, particularly in terms of sensitivity to change. It is possible that the longer history of administration may improve discussions with patients about their functioning over time. Furthermore, when the RAPID3 is used, an assessment of pain is included, addressing another patient priority domain with existing workflows. Functional status is commonly measured in rheumatology clinics, and the proposed measure aligns with an existing measure for rheumatoid arthritis,[31] which increases the feasibility of implementation. While not formally rated, workgroup participants also discussed and favored the actionability of PRO measure results in clinical practice. They highlighted that identifying patient functional concerns and challenges could lead to interventions such as physical therapy, occupational therapy, exercise or water therapy, joint bracing and recommendations for mobility or functional aids, and/or treatment changes to improve disease control or pain management.

The depression measure is the first ACR-based PRO quality measure that addresses mental health screening. Depression is highly prevalent among individuals with SLE,[26,27,48] and it may impact other health outcomes, including pain, physical function, cognition, work ability, and overall health and quality of life.[49,50] Moreover, again, it is highly actionable for treatment. Depression can also be associated with lower treatment adherence,[51] which may impact other disease outcomes. While it was initially somewhat surprising that depression was selected over other SLE-specific measure sets, we heard a strong narrative from patient partners regarding the impact of identifying and treating depression. Both panels also believed that identifying depression could lead to appropriate referrals to mental health resources, professionals, and/or national lupus support groups, which could facilitate timely treatment and result in a significant public health impact. The Patient Health Questionnaire-8 (PHQ-8)[52] was endorsed as a preferred measure, but screening using a PROMIS Depression short form or CAT[53] or the PHQ-2,[54] followed by a longer version (PHQ-8 or PHQ-9[55]) if warranted, was also deemed acceptable. Given the PHQ-9 includes a question on suicidal thoughts, real-time evaluation of results is needed. Indeed, if clinicians choose this measure, careful implementation is recommended to ensure that results are acted upon during the clinical encounter, given the potentially time-sensitive nature and implications of identifying significant symptoms of depression.

After debate, the panel endorsed fatigue and cognitive function as optional measures, with PROMIS measures recommended for both. Both panels recognized the significant impact of these symptoms on patient quality of life; however, there was consensus that these were slightly less feasible to measure in routine clinical practice, and therapeutic interventions to address these symptoms were less well-established. There was also discussion about the interrelated nature of fatigue, cognitive function, and depression and how identification and management of physical function and depression at a minimum, may lead to management strategies that could help improve clinical status in these other domains.[7] While pain was rated as important to assess, it is not included in the recommended measure for two primary reasons. First, an informal analysis of RISE data showed that pain measurements were reported and easily accessible in almost three quarters of SLE clinical encounters. Therefore, the public health impact of adding a quality measure addressing the measurement of pain was viewed as having minimal impact. Secondly, none of the pain measures examined resonated with the Patient Advocacy Panel. Thus, attention is needed to develop a pain assessment measure that may be more meaningful to SLE patients.

The intent of these measures is to set a minimum standard for collection of PRO quality measures. The Expert Workgroup unanimously voted to specify measurement of each quality indicator at least once in the measurement year, primarily based on the feasibility of implementation. While some practices will have procedures in place to administer the measures more frequently, particularly the MDHAQ, some may have more difficulty implementing and responding to the results of the measures. It is also possible that some patients do not adhere to a regular visit schedule or will not regularly complete the questionnaires. While the Patient Advisory Panel originally voted to assess measures at each clinical visit or monthly, after discussion, there was consensus on the measurement frequency specified in the measure.

While we used a multi-phased approach to reach our recommended measurement set, some limitations remain. We leveraged existing expert reviews of the literature to identify existing PRO instruments. In past ACR measure development work, we have conducted de novo systematic reviews to identify PRO instruments and psychometric validity literature.[31] Given the strong emphasis on the clinical feasibility of implementing the measures, we elected to start with existing expert reviews of measures based on the prioritized domains. We supplemented this with targeted searches for existing evidence and expert review. While it is possible this process missed existing literature on available PROs or their psychometric properties, given the emphasis on the feasibility of implementation in clinical practice and patient prioritization of domains, it is unlikely this would have significantly impacted the outcome of our process. As with any consensus process, it is possible that a different group of panelists may have reached a different set of priorities and/or measures. This may be particularly relevant for the patient partners. All individuals who participated in the project were identified through lupus advocacy groups, and it is possible that they may have had different experiences in their lupus care or history compared to patients without such involvement. Yet, our two panels provided diverse perspectives and experiences, and there was little disagreement between or within panels on the domain priorities or final recommended measures. Moreover, extensive patient involvement increases confidence that individuals living with lupus will find these recommendations acceptable during their health care encounters. All participants in the development process are from the US; it is possible that patients or physicians from other parts of the world may have different perspectives on the selection of domains or measures. An additional limitation is that these recommendations apply only to adult SLE patients. Work to extend this quality indicator to pediatric SLE patients is encouraged.

Conclusions

Lupus, a complex multisystem disease, has significant variation in patient experience. While clinicians are often focused on organ disease activity and damage, outcomes that are highly relevant and important to patients can be missed, leading to poor overall quality of life. Depression and physical function are two priority domains in SLE that correlate with outcomes, with well-established PRO metrics selected for quality measure development and implementation by the ACR.

Future goals include implementing the measures in the national RISE rheumatology registry to facilitate widespread uptake and implementation, coupled with an implementation plan incorporating proven quality improvement best practices to respond to measure screenings.[36] Steps toward those goals will include pilot implementation trials to evaluate the feasibility of measurement in different clinical settings and developing materials to assist in interpretation of PRO scores. These efforts will then inform broader recommendations on best practices and the developing guides and workflows to share with providers, staff, and administrators in busy, real-world practice. Additional action strategies that will be considered during the implementation of the measures include curating local and national resources for mental health and physical function and activity, facilitating access to support groups or other resources to aid in empowering patients, and developing management

strategies. Evaluating the impact of screening on care processes, access to resources, and patient outcomes should be assessed in future work.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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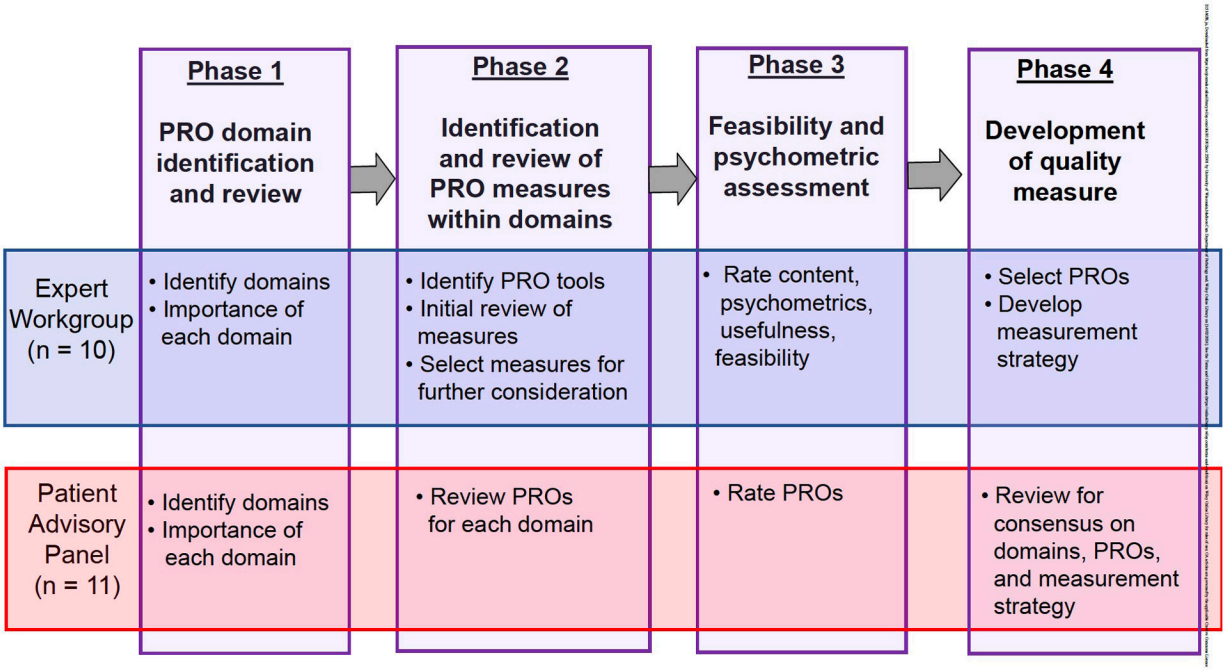

Figure 1.
SLE Workgroup Scope of Work for the Development of PRO Quality Measures in SLE

Table 1.

Patient-reported domains identified in literature review

Domain	Description or Components	% (n) of studies in which domain was mentioned (n = 25)	Type of domain
Fatigue	extreme tiredness, energy level	100 (25)	Generic
Pain	joint pain, muscle pain, general pain	96 (24)	Generic
Function	ability to perform daily activities, disability	80 (20)	Generic
Emotional/mental health	depression, anxiety, helplessness	80 (20)	Generic
Productivity	(limited productivity, work loss, impact on employment and career)	80 (20)	Generic
Social	social roles, social interactions, social support	72 (18)	Generic
Skin	rash, pigmentation, photosensitivity	72 (18)	Lupus-specific
Body image	hair loss, general aesthetics	64 (16)	Lupus-specific
Cognitive	concentration, memory, “brain fog”	56 (14)	Generic
Reproductive	fertility, pregnancy, sexuality	48 (12)	Lupus-specific
Dependence	Reliance on others, need for help, feeling like a burden	44 (11)	Generic
Sleep	poor quality sleep, disturbed or unrefreshing sleep)	36 (9)	Generic

(Domains identified in ≥25% of articles)

Table 2.

Workgroup and patient rankings of domains important to assess during routine clinical care

Expert Workgroup	SLE Patient Advisory Group
1. Fatigue	1. Pain
2. Pain	2. Physical function
3. Mental health	3. Fatigue
4. Physical function	4. Mental health
5. Cognition	5. Cognition
6. Social function	6. Sleep
7. Employment	7. Skin
8. Body image	8. Body image
9. Sleep	9. Social function
10. Reproduction	10. Employment
11. Skin	11. Reproduction

Table 3.

Measures reviewed for each domain and ratings of each

	Median workgroup ratings (Each attribute was rated on a 1–9 scale, with 9 being the most positive)				
	How well measure captures symptom	**Psychometric quality**	**Importance to clinicians**	**Importance to patients for self-management**	**Feasibility**
Function					
SF-36 Physical Function subscale	5.5	6	6	6	5
MDHAQ (Function)	5	4	5	5	6
PROMIS Physical Function (PF-10A)	8	8	7	7	7.5
PROMIS Physical Function (4-item)	6.5	6	6	6.5	9
Pain					
Single item pain severity	6	3	5	7	7
SF-36 Bodily Pain subscale	6	6	7	6	7
PROMIS Pain Interference	8	8	8	8	7
Fatigue					
Single item numeric rating	7	6	6	7	9
Functional Assessment of Chronic Illness Therapy -Fatigue (FACIT-F)	8	8	6.5	7	3
SF-36 Vitality subscale	5	5	5	5	6
PROMIS Fatigue	9	9	7	8	7
Depression					
Centers for Epidemiologic Studies-Depression (CESD)	5	6	6	6	3
Patient Health Questionnaire (PHQ-8)	7.5	7	7	7	7
PROMIS Depression	6	7	6	6	7
Anxiety					
Generalized Anxiety Disorder questionnaire (GAD-7)	7	7	7	7	7.5
PROMIS anxiety	7	7	6	6	7
Cognition					
PROMIS Cognitive Function – Abilities	6	6	6.5	6	7
PROMIS Cognitive Function	6	5.5	6	6	6.5
Social					
SF-36 Social Role subscale	4	5	3	3.5	6
PROMIS Ability to Participate in Social Roles and Activities	6.5	6	4.5	5	5.5
PROMIS Satisfaction with Participation in Discretionary Social Activities	6	7	3	5	5
PROMIS Satisfaction with Participation in Social Roles	7	7	4	5	4
Quality of life					

	Median workgroup ratings (Each attribute was rated on a 1–9 scale, with 9 being the most positive)				
	How well measure captures symptom	**Psychometric quality**	**Importance to clinicians**	**Importance to patients for self-management**	**Feasibility**
Lupus-specific					
Lupus Quality of Life Tool (LupusQoL)	7	6	5	5	1
Lupus Patient-reported Outcomes (LupusPRO)	6.5	6	5	5	3
Lupus Impact Tracker (LIT)	6	7	3	3	6
Generic					
SF-36	6	6	5	4.5	1
SF-6D	5.5	6	4	4.5	4.5

Table 4.

Patient preferred PRO surveys within the top domains

Domain	Patient Advisory Group Preferred Survey
Physical Function	PROMIS Physical Function (10-item) *MDHAQ was also evaluated because of its inclusion in the RAPID3*
Depression	PHQ-8
Fatigue	PROMIS Fatigue (7-item)
Cognition	PROMIS Cognitive Function
Pain	Single item pain scale and PROMIS pain interference were evaluated. Neither resonated with the group

Table 5.

Final SLE-PRO workgroup recommendations

Recommended Domains[a]	Preferred measures[b]	Additional acceptable measures	Notes
Physical function	PROMIS Physical Function 10A or CAT		
		MDHAQ	MDHAQ is included in the RAPID 3, which is already in the workflow of many practices
Depression	Patient Health Questionnaire (PHQ)-8		If PHQ-8 score ≥10, follow-up with real-time evaluation of patient.
		PHQ-2[54]	PHQ-2 has excellent correspondence with PHQ-9. If score is ≥3, should be followed with longer version.
		PHQ-9	PHQ-9 includes suicidality item. If used, should be reviewed in real time for immediate evaluation.
		PROMIS Depression short form or CAT[56]	If PROMIS measures are embedded in the EHR or a digital application, CAT administration would be acceptable. If score ≥8 or T-score ≥55), follow-up with evaluation of patient.
Optional domains			
Fatigue	PROMIS Fatigue 7 or CAT	Other PROMIS fatigue short form versions	
Cognition	PROMIS Cognitive Function	Other PROMIS cognitive function short forms	

[a] Pain is not included because (1) a review of the RISE registry indicated that pain was already assessed and reported in an easily retrieval structured field easily retrievable in 73.5% of SLE visits, and (2) none of the pain measures reviewed resonated with the patient group.

[b] Preferred measures were selected based on ratings of psychometric quality, usefulness, and feasibility by physician workgroup and preference ratings by patient focus group.