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Special Article

Vitales project: Consensus on measuring health outcomes for better integrated management of patients with systemic lupus erythematosus

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ABSTRACT

Introduction: Systemic lupus erythematosus (SLE) is one of the most common systemic autoimmune diseases. It presents with a heterogeneous clinical picture and can cause irreversible damage. Its clinical manifestations vary over time, affecting different organs. This variability makes it complex but necessary to monitor, in a standardised and objective way, the manifestations of the disease through validated instruments that determine the degree of activity and the damage associated with the disease.
Objective: To define, through a national consensus, the standardisation of the measurement of health outcomes in SLE with the aim of improving the comprehensive control of patients with this disease.
Conclusions: The measurement of health outcomes in three major domains: disease activity, disease burden and quality of life, could help improve the control of the disease in patients with SLE from a comprehensive perspective, as well as obtaining information on the established therapeutic objectives and therefore allowing better clinical decisions to be made.

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Proyecto vitales: Consenso en la medición de resultados en salud para un mejor control integral de los pacientes con lupus eritematoso sistémico

Palabras clave:
Lupus eritematoso sistémico
Resultados en Salud
Calidad de vida
Actividad de la enfermedad
Daño

RESUMEN

Introducción: El LES es una de las enfermedades autoinmunes sistémicas más frecuente. Presenta una clínica heterogénea y puede generar daño irreversible. Sus manifestaciones clínicas varían a lo largo del tiempo, afectando a diferentes órganos. Esta variabilidad hace que sea complejo pero necesario monitorizar, de forma estandarizada y objetiva las manifestaciones de la enfermedad a través de instrumentos validados que determinen el grado de actividad y el daño asociado a la enfermedad.

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Objetivo: Definir, a través de un consenso nacional, la estandarización de la medición de resultados en salud en el LES con el objetivo de mejorar el control integral de los pacientes con esta enfermedad.
Conclusiones: La medición de resultados en salud en tres grandes dominios: actividad de la enfermedad, carga de la enfermedad y calidad de vida, podría ayudar a mejorar el control de la enfermedad de los pacientes con LES desde una perspectiva integral así como obtener información sobre los objetivos terapéuticos establecidos y por tanto, permitiría tomar mejores decisiones clínicas.
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Introduction

Systemic lupus erythematosus (SLE)[1] is one of the most common systemic rheumatic diseases and its incidence is increasing. In Spain, it is estimated to affect nine out of every 10,000 people.[2] According to data from the RELESSER-T platform on SLE patients,[3] 90% of cases are in women, 93% are Caucasian, the median age at diagnosis is 33 years, and 53% of patients have been hospitalised at least once. SLE is a heterogeneous disease whose activity varies over time, and which can cause irreversible damage. It is not characterised by a single main manifestation, but rather several organs may be affected with varying prognostic significance as a direct consequence of the disease. This means that many factors must be considered during follow-up. This variability necessitates monitoring the manifestations of the disease in a standardised and objective manner using validated instruments that determine the degree of disease activity and associated damage.[4]

The simplest tool for assessing activity in daily clinical practice is the physician's overall assessment. However, this is subject to significant inter-observer variability.[4] An alternative is the use of scales or indices, which has been shown to be an effective method of measuring SLE activity. It is also known that these scales are capable of predicting damage and mortality,[5] but there is currently no agreement on their use in routine clinical practice as they are not feasible in routine clinical practice. Most of these scales were created to evaluate the efficacy of drugs in clinical trials. This hinders the establishment and updating of clinical guidelines and the improvement of standardised patient follow-up, as it makes it almost impossible to compare health and quality of life (QoL) outcomes in SLE at the national level.

It is necessary to define the objectives to be achieved in SLE follow-up.[6,7] In addition to reducing mortality, damage accumulation should be prevented, treatment toxicity minimised, and patients' quality of life improved. Achieving these objectives should demonstrate an impact on health outcomes.[6]

Justification

Measuring health outcomes enables us to focus on the patient and evaluate results from the perspective of both clinical indicators and patient expectations, a variable that is often overlooked. Although measuring health outcomes is already a reality in Spain, this has not progressed at the same pace in all specialities and/or pathologies. In the field of immune-mediated diseases, diseases such as rheumatoid arthritis have achieved broad consensus among professionals regarding the clinical variables to be measured and the need to include quality of life (QoL). However, this does not seem to be the case with lupus, where the measurement of health outcomes has not been systematised or standardised. This is possibly because evaluating patients with SLE is challenging for various reasons. This is due to the complex multisystemic involvement caused by the disease, as well as its fluctuating course, meaning that patients have very different outcomes and levels of involvement.

For all these reasons, and given the opportunity to bridge the existing gap, it is clear that a consensus must be reached among SLE experts at a national level on which health outcomes should be measured in order to improve disease control. This would aid therapeutic decision-making in clinical practice for the benefit of patients, while also raising awareness among professionals of the importance of measuring health outcomes in SLE.

Objectives

The objective is to define, through national consensus, the standardisation of health outcome measurement in SLE, with the aim of achieving better, more comprehensive control of patients with this disease.

Material and methods

The concepts to be defined were defined and selected through a structured work process that was developed in four main stages described in Fig. 1. 1) Search and analysis of current evidence; 2) Definition of criteria and objectives by the advisory group; 3) Workshop phase; and 4) Delphi phase.

In addition, the endorsement and/or collaboration of various scientific societies and patient associations was obtained: Spanish Society of Rheumatology (SER); Spanish Society of Internal Medicine (SEMI); Spanish Society of Dermatology and Venereology (AEDV); Spanish Society of Nephrology (SEN); Spanish Society for Healthcare Quality (SECA); Spanish LUPUS Federation (FELUPUS); Spanish Society of Hospital Pharmacists (SEFH); Spanish Federation for Quality in Healthcare (FECA); Spanish Society of Family and Community Medicine (SEMFYC).

Expert advisory group

The project had an advisory group comprising clinicians specialising in SLE from the fields of rheumatology, dermatology, nephrology, and internal medicine, as well as managers and pharmacists. A representative of SLE patients from the FELUPUS association also participated in the group, as did an expert rheumatologist who served as the project coordinator.

Phase 1: Search and analysis of current evidence

A literature search was conducted in this first phase to identify the existing literature on the different scales and measurement tools used in SLE, as well as the correlation between them. The available evidence was analysed in terms of the validity of each item for use separately or in combination. The search strategy is detailed in Table 1.

The literature search returned 233 records. After removing duplicates, 222 records were evaluated.

Based on the literature found, articles that met the following criteria were selected:

- The objective of the study should be to validate or compare the measurement of disease activity and/or damage using the currently validated different indices and scales.
- The article should provide useful information on some of the scales, comparing or analysing them.

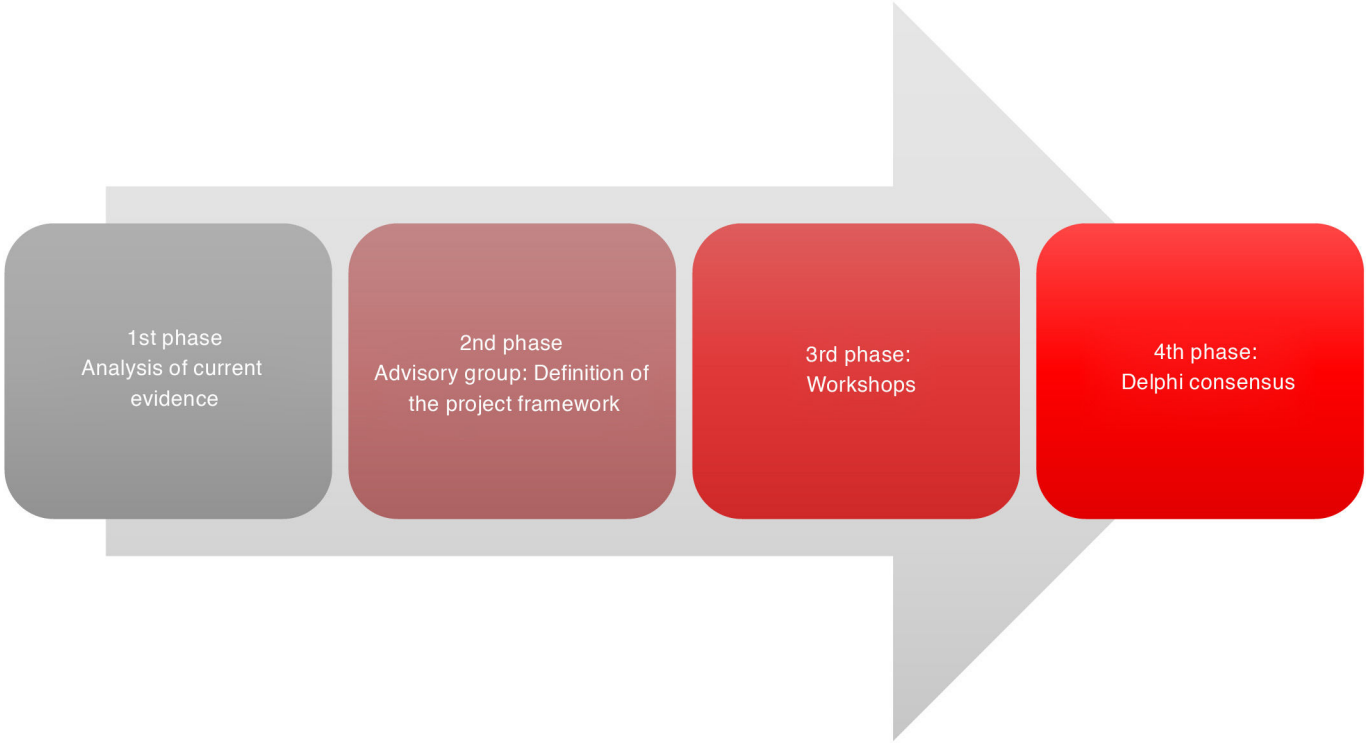

Figure 1. Project phases.

Table 1
Search strategy.

Database	Key words	Filters	Results
Pubmed	("Lupus Erythematosus, Systemic" [Mesh] AND "outcome measure" AND "activity disease")	10 years Spanish, English Systematic reviews, Meta-analyses, Clinical studies	168
Dialnet	Lupus erythematosus AND activity disease OR disease damage AND outcome measure	10 years Spanish, English Journal articles	1
Scopus	(TITLE (Systemic lupus erythematosus) AND TITLE (Activity disease) AND TITLE-ABS-KEY (Measure))	10 years Spanish, English Area of medicine Reviews and articles	64

- The conclusions reached by the study provide greater insight into the subject and can serve as a reference for the objectives of the VitaLES workshop for clinicians.

Articles that use disease activity scales in the evaluation of a drug's efficacy, but whose objective is not the measurement or analysis of the validity, comparability and/or usefulness of the scale, were discarded. Studies validating any of the scales in a new language or adapting a scale to specific populations were also discarded.

Four articles that met the search criteria were selected as a result of this synthesis:

- Measuring disease activity and damage with validated metrics: A systematic review on mortality and damage in systemic lupus erythematosus. O Keeling et al. 2018.
- Clinical composite measures of disease activity and damage used to evaluate patients with systemic lupus erythematosus: A systematic literature review.[13]
- Indices to assess patients with systemic lupus erythematosus in clinical trials, long-term observational studies, and clinical care. Castrejon et al., 2014
- From BILAG to BILAG-based combined lupus assessment-30 years on. Murphy et al., 2016.

The most important conclusions from these articles were shared with group participants prior to the workshop.

Phase 2: Definition of criteria and objectives by the advisory group

In this phase, the advisory group agreed on the profiles of the workshop participants and the practical objectives to be achieved in each workshop, as well as the criteria for participation and agreement in the Delphi phase, and the general framework for action.

Specifically, it was decided to hold four multidisciplinary working meetings including SLE patients, in which the conclusions of each workshop would form the basis for the next one. This would ensure that everyone's contribution added to the final result. The objective of the workshops was for participants to reach a consensus on issues such as what constitutes comprehensive control, which health outcomes should be measured and which validated

Table 2
Number of participants by profile in the workshops and Delphi consensus.

	1st Workshop	2nd Workshop	3rd Workshop	4th Workshop	Delphi	Total
Profiles	Patients	Rheumatology Interna. M. Dermatology Nephrology Primary Care	Pharmacy Quality Managers	Rheumatology Interna. M. Dermatology Nephrology Primary Care Nursing Pharmacy Quality Managers	Rheumatology Interna. M. Dermatology Nephrology Primary Care Nursing Pharmacy Quality Managers Patients	
N. of participants	6	9	9	36	173	233

tools, scales, or indices are most appropriate for the practical management, control, and follow-up of patients with SLE.

Regarding the criteria for the Delphi phase, it was agreed that Trevelyan's recommendations would be followed.[8]

Phase 3: Workshops

Four workshops were held. Prior to each workshop, participants were sent a report on the evidence found and the project objectives, to serve as a basis and aid in the development of the workshop. This preliminary report also included the conclusions reached in previous workshops, enabling the final report to draw on contributions from the various working groups.

The first workshop was attended by a group of SLE patients who, using the focus group methodology[9] created a 'patient journey map' or SLE patient pathway. This identified unmet needs and set out which health outcomes were important for patients' quality of life (QoL) and should therefore be collected as patient-reported outcomes (PROMs). The focus group,[9] methodology was chosen because of its advantages in terms of the quality of information obtained.

Analysis process

During an open and participatory debate, a series of questions were raised to address various issues related to the objectives of the workshop:

1 Definition of the pathway. Key points
2 Identification of unmet needs
3 Health outcomes that matter to patients with SLE

The second workshop comprised a group of clinical experts (Table 2). This working session included a presentation of the analysis of evidence found in the scientific literature, as well as the conclusions of the previous workshop with patient representatives. All of this information formed the basis for reaching a clinical consensus on which aspects of the disease should be measured, and which tools are considered the most useful, reliable and valid for monitoring patients with SLE.

The third workshop was attended by a group of managers, pharmacists, and evaluation and quality experts (Table 2). This working session included a presentation of the conclusions from the patient and clinician workshops, and aimed to reach a consensus from the perspective of evaluators and decision-makers on which aspects of the disease should be measured, and which tools are considered the most useful, reliable, and valid for monitoring patients with SLE.

Finally, the fourth workshop took place. This workshop had a larger group of participants than the previous ones. The reason for holding this workshop with an expanded multidisciplinary group was the need to have a joint vision of all the profiles involved in the pathology. For this reason, the group was expanded, in terms of both number and profiles (Table 2). Based on the conclusions of the workshops with patient representatives, clinicians, and decision-makers presented above, the participants in this multidisciplinary workshop reached a final consensus on which aspects of SLE should be measured, which tools are most appropriate, and the frequency of measurement for better control, management and monitoring of the disease.

Phase 4: Delphi consensus

The conclusions reached in the workshops, once analysed and reviewed by the advisory group, were brought to consensus by an expanded group of professionals and patient representatives according to the Delphi methodology, following Trevelyan's recommendations.[8] The Delphi consensus process was carried out via a survey, with different numbers of questions for professionals and patients. The latter were not sent questions on clinical decisions specifically (Appendix I and II). The survey was designed with a defined number of questions on items assessed and agreed upon in the workshops, asking respondents to indicate whether they agreed or disagreed with each one. Responses were evaluated using a Likert scale with scores from 1 to 5, where 1 indicates total disagreement and 5 indicates total agreement.

The Advisory Group set the minimum required level of participation at $\geq$60%, stipulating that it should not be less than 50% for each profile. To this end, the participation percentage for each profile and each round was monitored from the outset. The degree of consensus required for a recommendation to be considered relevant was also set at greater than 70%, in accordance with Humphrey-Murto et al.[10] In an attempt to improve consensus, the required percentage was set at 80% in the first round and 75% in the second. For this purpose, responses corresponding to 'agree' or 'strongly agree' were considered positive, while the rest were not.

The selected panellists were invited to participate via email. After they accepted, an email was sent with a link to a Google platform website where they could access the questionnaires. Participants generated their responses individually and anonymously.

1st Delphi round

A sample of 200 people (professionals and patients) was selected. Professionals were selected on the basis that they should have profiles directly related to the care of SLE patients in any of their fields: doctors, nurses, and pharmacists. Managers, quality experts, and patients from the FELUPUS association were also included. The proportion of participation for each profile was intended to match the same proportion as that of the 4th workshop. Multidisciplinary. It was considered that 200 invitations was an ideal number to achieve a minimum participation of 120/130 people.

Table 3
Participant sample by profile.

Profile	% participation	N. of participants
SLE patients	20%	15
PC physicians	80%	6
Dermatologists		9
Internal M.		18
Nephrologists		9
Rheumatologists		18

Once the Delphi methodology had been agreed with the advisory group, a questionnaire with 14 questions was drawn up (Appendix I), which included the following content:

1 **Scale**: content and measurement.
2 **Definition of disease control:** what it includes.
3 **Usefulness and feasibility of the scale in clinical practice.**
4 **Domains of health outcome measurement**: what it should include.
5 **Quality of life:** domains, questionnaires, and frequency of measurement.
6 **Cumulative harm:** when to measure.

The questionnaire was developed based on the working groups' conclusions. If the percentages previously decided by the Advisory Group were not reached in the first round, a second round would be necessary.

2nd Delphi round

Once the responses from the 1st round had been collected and analysed by the advisory group, it was decided that a 2nd round should be carried out to explore those issues that had not achieved the required 80% threshold in greater depth.

The following criteria were established for this round: the number of participants should reach a minimum of 75, and given that the issues pending consensus (Appendix II) affected decisions within the clinical sphere and the patient's QoL, the advisory group defined that participants should belong to medical specialties directly related to the treatment of SLE and to patients (FELUPUS). The agreed distribution percentages were 20% for patients and 80% for clinicians, as shown in Table 3.

Results

The results of the various workshops are as follows:

Results of the workshop with patients

Patients described their 'patient journey map' and, as a result, expressed unmet needs from their perspective as patients. These included the need for coordinated multidisciplinary care with consistent criteria for all professionals treating them, adequate information and training for patients and families, and a voice within the healthcare system. Regarding the PROMs that should be collected and considered when making shared decisions, they concluded that the following should be measured: emotional state, pain, stress, functional capacity, socio-occupational issues, asthenia/fatigue, and sexuality. They considered the Fatigue Severity Scale (FSS)[11] and the SF12 and SF36 QoL questionnaires suitable for reporting these items.[12]

Results of the clinical expert workshop

The main conclusion of the SLE clinical expert workshop was that the standardised tools currently available for assessing disease activity are not suitable for use in routine clinical practice and their usefulness is limited to compliance with registries and clinical trials. The experts then agreed on the characteristics that an activity scale should have in order to be useful in therapeutic decision-making and to help achieve the therapeutic goal of remission, and therefore be useful in clinical practice. They concluded that this tool should be straightforward and easy to use, should not take long to complete, and should be easy to interpret. Based on these premises and using the items from the SLEDAI/LAI-P scales[13] as a basis, they developed a proposed scale, which is detailed in Table 4. A health-related quality of life (HRQoL) assessment, measured using one of the currently validated scales, should be added to this SLE disease activity scale.

Results of the workshop for managers and decision-makers

After analysing the results obtained in previous workshops, the participants made the following contributions: in addition to QoL and disease activity, adherence, and adverse effects of medication should also be measured. They also agreed that values indicating remission and exacerbation must be defined in order to make therapeutic decisions.

Results of the multidisciplinary workshop

The working group decided that measuring SLE activity is as important as measuring QoL or cumulative damage. Therefore, an agreement was reached on the domains to be measured in SLE. This set of health outcomes includes the following fields, as described in Fig. 2.

It was unanimously agreed that 'treatment adherence' should be measured using the Morinsky Green scale.[14] However, there was no unanimity on the QoL measurement scale: 65% of participants voted for SF-12 and 35% for EQ-5D.[15] Nor was there consensus on establishing the frequency of QoL measurement and, specifically, whether it should be measured when there was a flare-up or one month after a flare-up.

The final results obtained at this multidisciplinary meeting, which also included the partial results of each workshop held, were brought to Delphi consensus.

DELPHI consensus results

In the first round, the survey was answered by 19 patients and 154 professionals, thus meeting the minimum participation agreement of 100.

The participation result by profile is shown in Fig. 3

The result of the questionnaire consensus (Appendix I) was as follows:

An 80% consensus was not reached on the following responses:

- In the selection of the QoL scale.
- In the following domains to be measured: sexuality, body image, mood and relationships within QoL.
- In the questions referring to the assessment of disease activity and control scale proposed by clinicians, in terms of whether it is suitable for use in patient follow-up and whether it facilitates therapeutic decision-making.

Table 5 shows the percentage of consensus reached on each question in detail:

These questions therefore needed to be taken to a second round (Appendix II), the results of which were as follows:

Table 4
Proposed scale to measure SLE disease activity.

Clinical picture 1(A)	Partial score					Overall score
Fever	0	1				HIGHER
Arthritis	0	1	2	3		
Lupus-specific mucocutaneous lesions	0	1	2	3		
Non-scarring alopecia	0	1	2	3		
Myositis	0	1	2	3		
Serositis	0	1	2	3		
CLINICAL PICTURE 2(B)						
Renal involvement	0	1	2	3	4	HIGHER
Neuropsychiatric involvement	0	1	2	3	4	
Pulmonary involvement	0	1	2	3	4	
Haematological involvement	0	1	2	3	4	
Vasculitis	0	1	2	3	4	
LABORATORY (C)						
C3	0	1				HIGHER
C4	0	1				
Anti-DNA n	0	1				
TREATMENT (D)						
Prednisone ≤ 5 mg/day	0					HIGHER
Prednisone 5.1–7.5 mg/day		1				
Prednisone > 7.5 mg /day			2			
Stable immunosuppressant	0					
New immunosuppressant			2			
Stable biological	0					
New biological			2			
QUALITY-OF-LIFE (E)						
Quality of life	0				10	HIGHER
TOTAL SCORE:	(A + B+C + D) E					

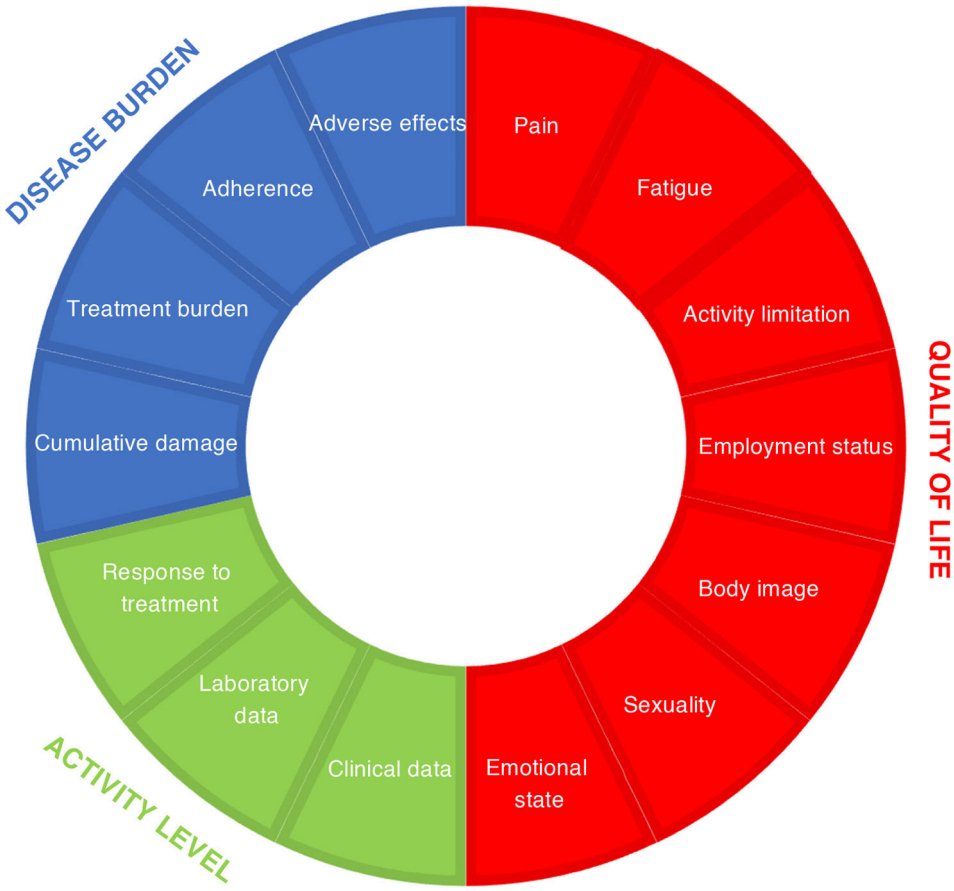

Figure 2. Health outcomes. Domains to be measured proposed in the multidisciplinary workshop.

- The survey was completed by 21 patients and 77 professionals, and the percentage of participation by profile was as shown in Fig. 4.

Regarding the question about the preferred QoL questionnaire for measurement, none of those presented obtained the 75% required to reach consensus, so it was left to the discretion of

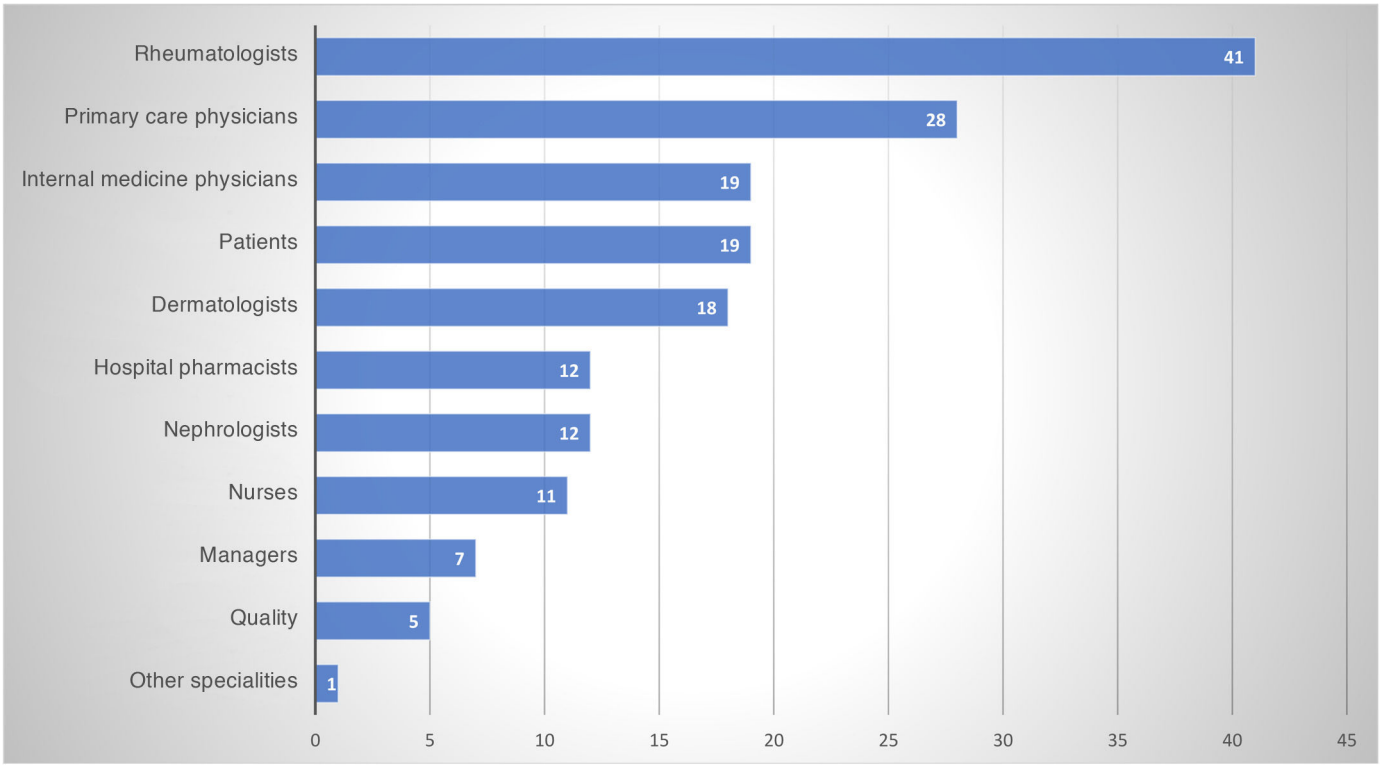

Figure 3. Number of participants by profile.

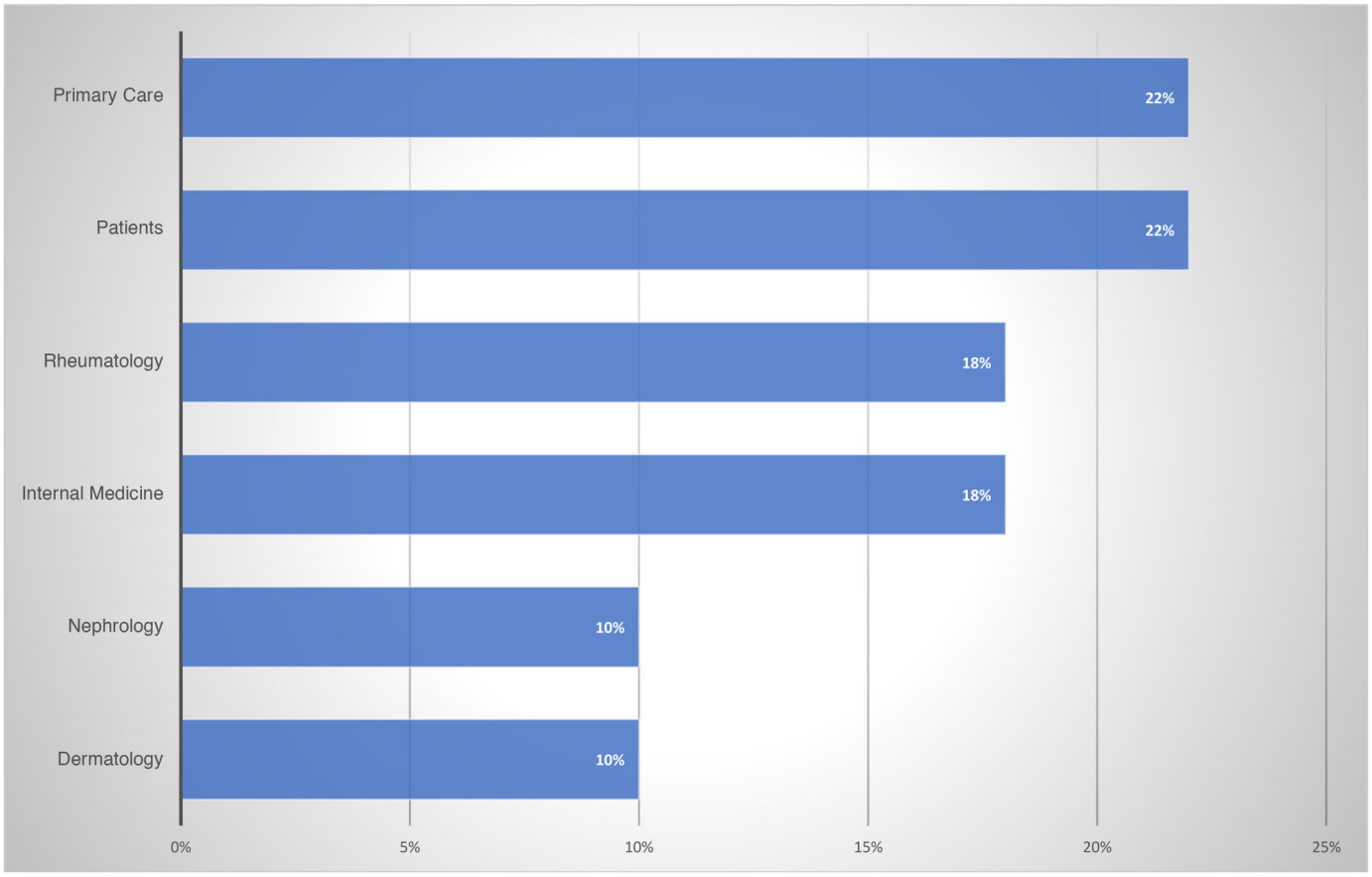

Figure 4. Percentage of participants per profile.

Table 5
Results of the Delphi questionnaire, 1st round.

Questionnaire		% Consensus (>80%)	% No Consensus (<80%)
The activity measurement scale should be useful in follow-up		94.3%	
The scale should be as simple as possible, and the result should be shown on a scale of 0 to 10:		87.2%	
It is necessary to validate and check consistency with existing and internationally validated scales.		97.9%	
The concept of disease control includes activity, treatment and quality of life.		94%	
The SLE control scale presented:			
	It is feasible in clinical practice:	82%	
	It includes the necessary points for assessing activity:	84%	
	It is suitable for use in patient follow-up:		78%
	It facilitates therapeutic decision-making:		73%
The concept of disease control includes activity, treatment, and quality of life.		94%	
The measurement of SLE health outcomes should include the following domains:			
	Quality of life (symptoms and functionality):	86%	
	Disease control (clinical data, laboratory data, and response to treatment):	87%	
	Disease burden:	85%	
The quality-of-life questionnaire to be used by SLE patients should assess the following domains:			
	Physical well-being:	91%	
	Mental well-being:	87%	
	Occupational:	82%	
	Sexual:		74%
	Mood:		77%
	Relational:		72%
	Body image:		71%
The CV questionnaire to be used in actual clinical practice, at least once a year, should be:			
	SF-12, because it is general, short and straightforward:		60%
	SF-36, because it is general and more comprehensive:		45%
	EuroQoL 5D, because it is the most widely used and shorter:		67%
Quality of life in SLE should be measured:			
	At least once a year:	87%	
	When there is a disease flare-up:		47%
	One month after each disease flare-up:		53%
To assess the therapeutic course, the following should be collected in a standardised manner in the CH:			
	All treatments received since the onset of the disease:	89%	
	At least the treatments received in the last 5 years:		70%
	Adherence to treatment:		76%
The cumulative damage caused by SLE in each patient (irreversible lesions and sequelae that appear during the course of the disease caused by its activity, by the treatments used or by other associated diseases) should be measured once a year:		93%	
A control scale for SLE patients should include the following data blocks			
	General signs and symptoms:		97%
	Organic signs and symptoms:		96%
	Laboratory data:		95%
	Treatment type:		96%
	Quality of life:		92%

each centre, recommending a generalist questionnaire from among those most commonly used in Spain (EuroQoL-5D, SF-12, LES-ESP, and EVA) containing the agreed QoL domains. Taking into account the results of clinicians and patients, the outcome is detailed in Fig. 5.

There were significant differences in the selection of questionnaires to measure QoL between clinicians and patients. Clinicians opted for quicker and easier questionnaires to complete, while patients opted for more comprehensive questionnaires containing a greater number of items, as can be seen in Figs. 6 and 7.

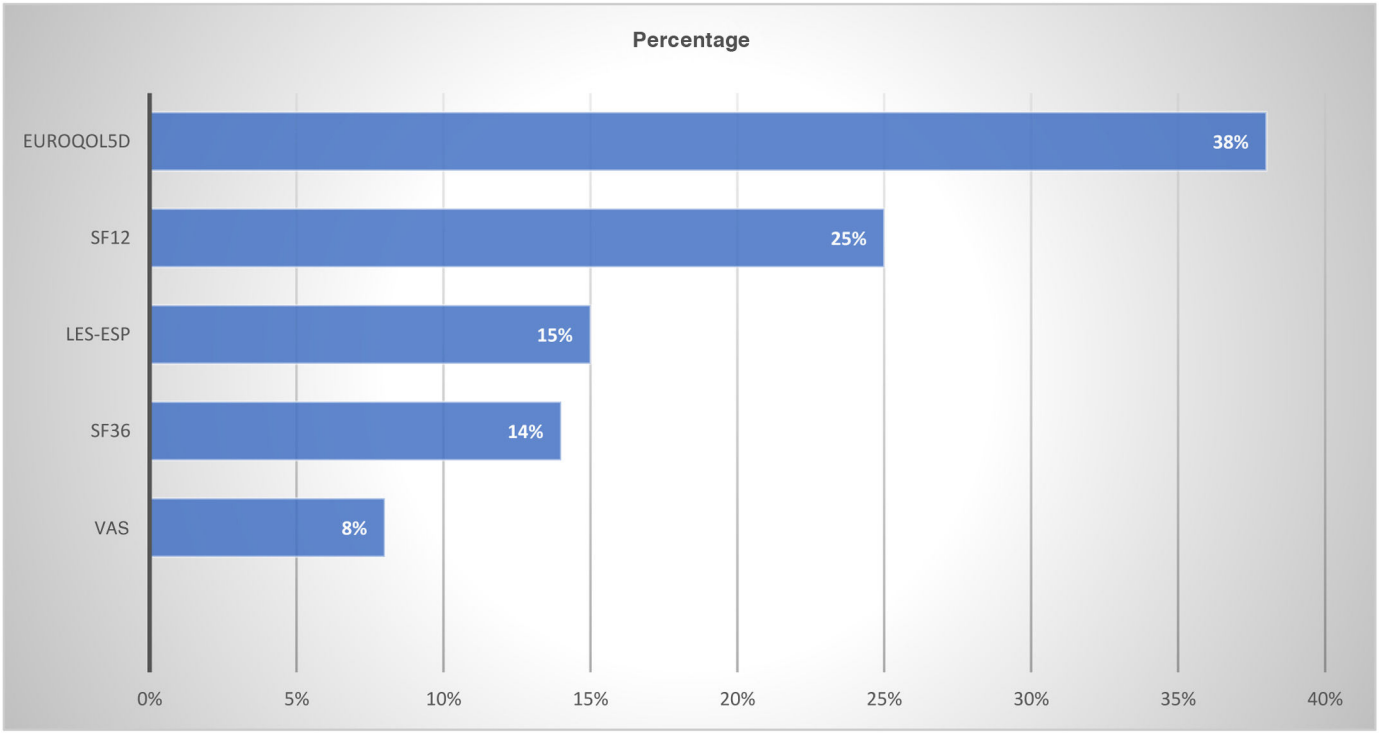

Figure 5. Choice of QoL questionnaire.

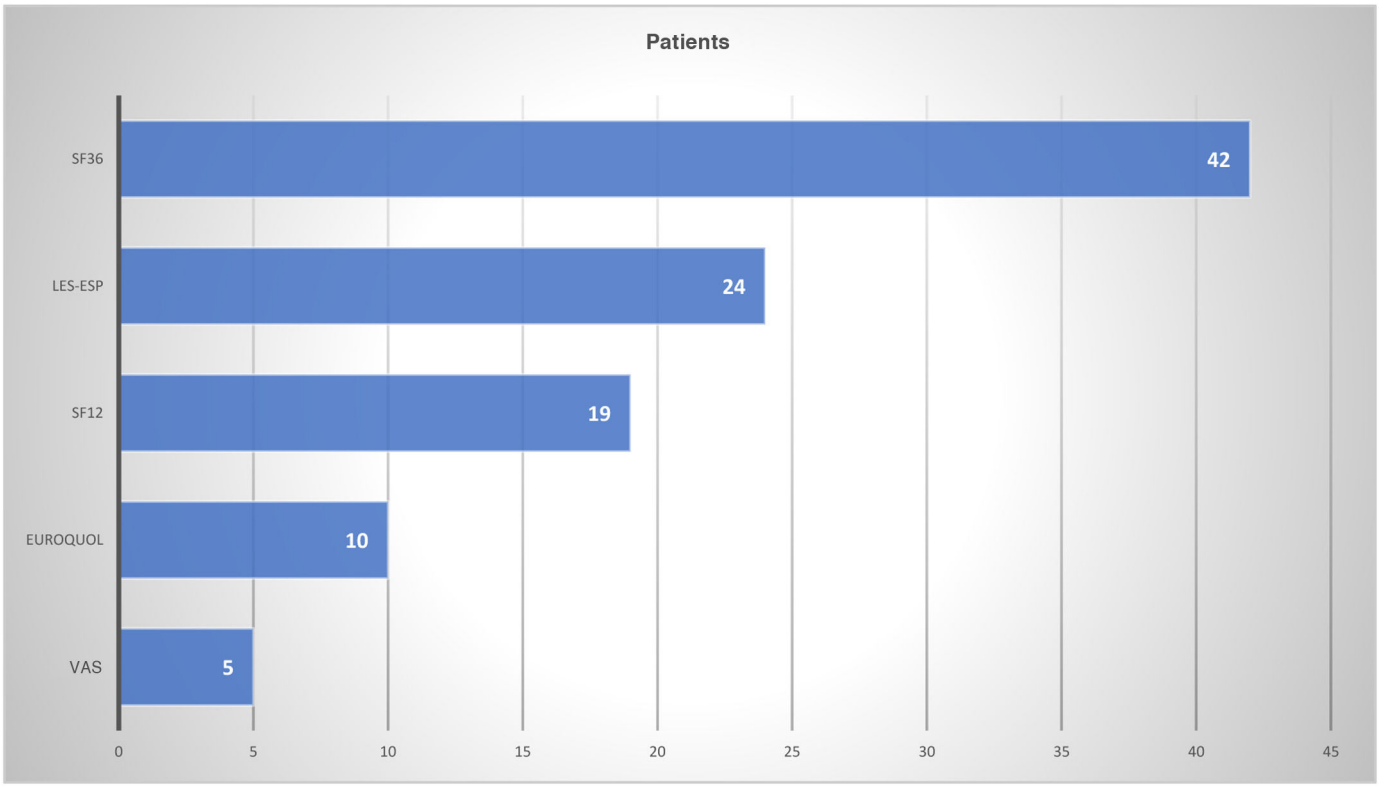

Figure 6. Choice of QoL questionnaire by patient.

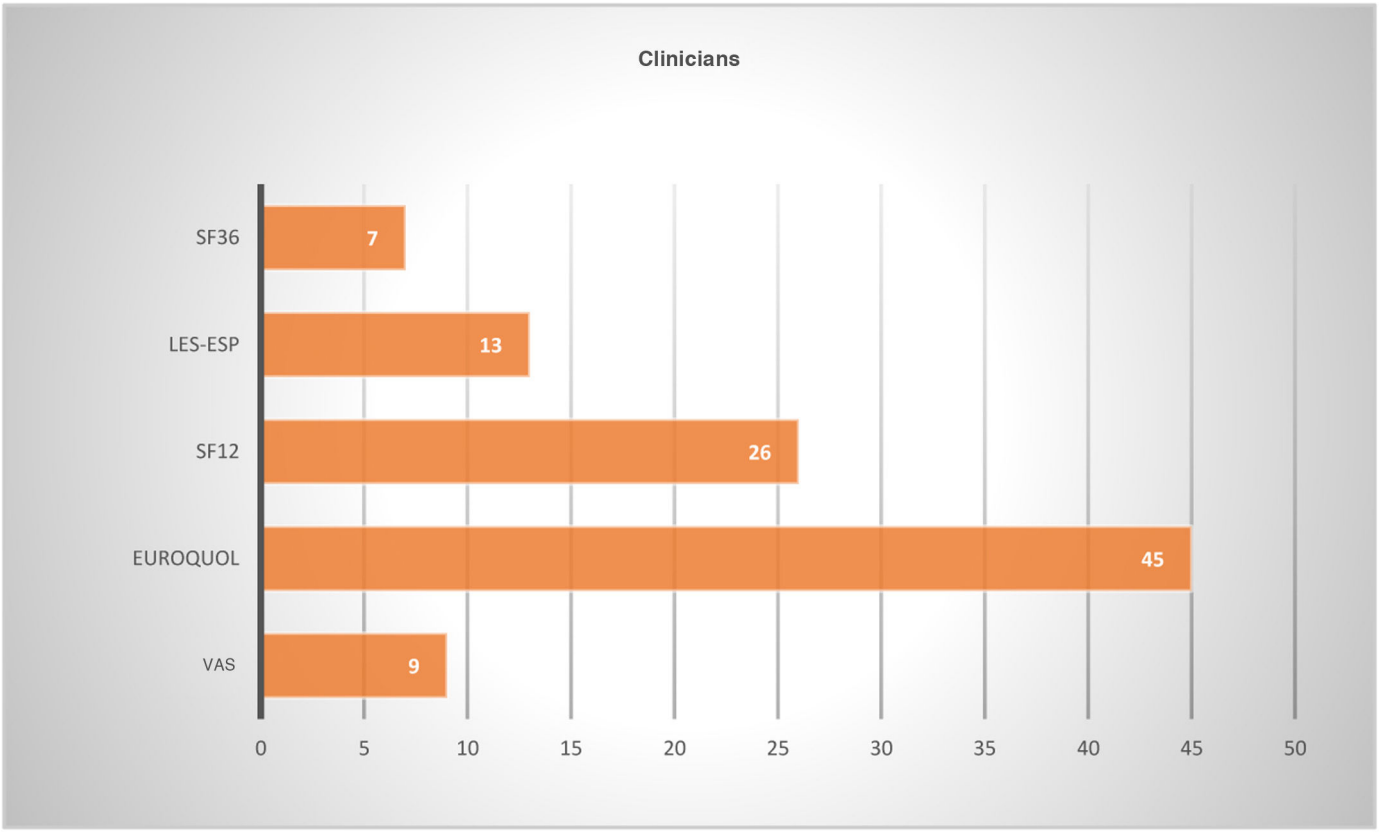

Figure 7. Choice of QoL questionnaire by clinician.

Consensus was reached on the following issues raised in this round:

- To the question whether the proposed scale is suitable for monitoring patients with SLE, 100% of respondents answered yes, it is suitable.
- To the question whether the proposed scale should preferably be included in the EHR in order to be practical and effective, 97% of participants responded that it should preferably be incorporated into the EHR, and within this percentage, 20% said that they considered it adequate even without including it in the EHR.
- To the question whether they thought the scale was big enough for making therapeutic decisions, 98.5% answered yes

For each domain, a sequence was proposed that describes when the data will be collected or reported during the course of the disease, and who will be responsible for doing so (patient and/or professional). This sequence is described in Fig. 8.

Discussion

The most relevant results of this study conclude that comprehensive monitoring of patients with SLE should involve measuring health outcomes. This measurement should cover three key areas: disease activity (clinical and laboratory data and response to treatment), QoL (including pain, fatigue, socio-occupational situation, and emotional state) and disease burden (accumulated damage and serious and permanent adverse effects of treatments).

No single specific questionnaire has been established for measuring QoL, and therefore each centre can use a generalised, accessible one provided the same questionnaire is used for each patient. The most commonly used questionnaires have been shown to produce consistent and comparable results. It is essential that the chosen questionnaire assesses the agreed domains of physical, mental, and emotional well-being and function, and is administered at least once a year. It is essential that the questionnaire used assesses at least the agreed domains in the areas of physical, mental, emotional and functional well-being, and that it is administered at least once a year.

Annual assessment is recommended for cumulative damage – understood as the irreversible injuries and sequelae caused by the disease, treatments, or comorbidities – using international questionnaires such as the SLICC/ACR or the DI,[16] ensuring that the same questionnaire is used for the same patient each time.

Regarding disease activity, given the variability in the current scales, experts should agree on a single measurement scale. This tool should be simple, practical and feasible for both patients and healthcare professionals, ensuring homogeneous and effective monitoring.

Standardising the measurement of health outcomes is one of the main challenges currently facing the provision of quality care. In addition to meeting therapeutic objectives, improving disease control and HRQoL is crucial. Measuring health outcomes promotes better clinical decision-making, enables benchmarking, optimises the monitoring of routine clinical practice, and provides valuable information for continuous improvement at all levels.[17]

In this regard, the monitoring and treatment of SLE should aim to ensure survival, prevent organ damage, and optimise QoL by controlling disease activity and reducing comorbidities and drug toxicity.[7]

It was considered essential to include the measurement of QoL through patient-reported PROMs and therefore patients were asked in advance what really matters to them beyond purely clinical aspects. This should be considered a step towards shared decision-making.[18]

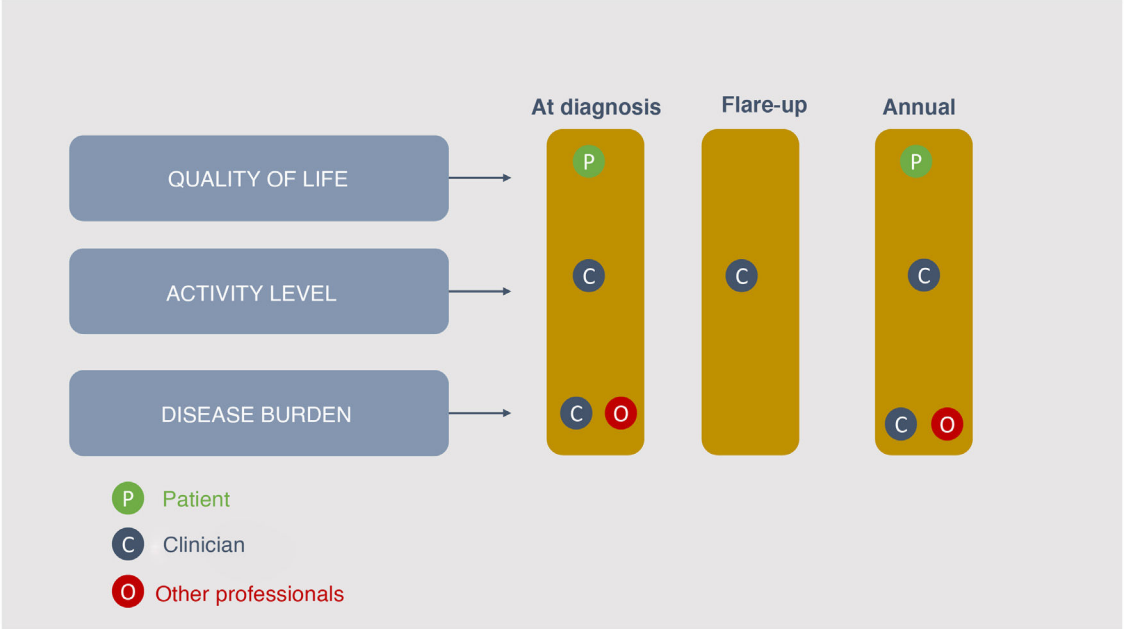

Figure 8. Summary table of timing and who should collect the data.

We believe that implementing health outcome measurement in routine clinical practice for SLE patients could help to improve disease control, enable better decision-making, and generate useful information for clinical practice, research, and management.

As future lines of research and/or work, there is an opportunity to continue standardising, systematising, and implementing health outcome measurement throughout Spain to avoid inequalities in the comprehensive care of patients with systemic lupus. This can only be achieved through collaborative efforts involving professionals working in this field, healthcare organisations, and patients.

Furthermore, since the use of the various validated scales in Spain is at the discretion of each centre or service, provided they measure the agreed domains, it is still possible to evaluate the correlation between the different dimensions of the proposed scales that have not yet been evaluated and published. This would enable a national comparison of health outcomes.

One open line of research is an observational, longitudinal, multicentre study recently launched with the aim of recruiting 150 adult patients with moderate-to-severe SLE. These patients will start the VitaLES programme within six months (October 2024 – April 2025) in 19 Spanish hospitals. Patients will be followed up for 12 months after starting VitaLES. The study will include comprehensive data on disease burden, disease activity, and quality of life (QoL) in patients with moderate-to-severe SLE. This will be measured using the VitaLES activity scale, the EQ-5D-5 L questionnaire, and the SLICC/ACR questionnaire. This study hypothesises that the VitaLES initiative will contribute to the standardisation of clinical practice, leading to more rigorous disease measurement in patients with SLE and improving disease control.

Another line of future research could involve comparing vitaLES with other current parameters.

Conclusions

This multidisciplinary study has highlighted the need for standardised measurement of health outcomes in SLE patients, including disease activity, cumulative damage and QoL.

Including PROMs is a fundamental step towards more patient-centred care and shared decision-making. Implementing these measurements in routine clinical practice could improve disease control, optimise therapeutic decisions, and provide valuable information for clinical practice, research, and healthcare management.

Furthermore, future standardisation and systematisation of these measures at a national level will reduce inequalities in care and help to achieve comprehensive, quality care for all SLE patients.

Finally, studies such as VitaLES provide a concrete opportunity to validate and expand these initiatives by offering evidence of their effectiveness and enabling comparisons with other existing tools.

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.reumae.2025.502022.

Declaration of competing interest

The authors have no conflict of interests to declare.

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