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REVIEW

Systemic lupus erythematosus: state of the art on clinical practice guidelines

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ABSTRACT

Systemic lupus erythematosus (SLE) is the paradigm of systemic autoimmune diseases characterised by a wide spectrum of clinical manifestations with an unpredictable relapsing-remitting course. The aim of the present work was to identify current available clinical practice guidelines (CPGs) for SLE, to provide their review and to identify physicians' and patients' unmet needs. Twenty-three original guidelines published between 2004 and 2017 were identified. Many aspects of disease management are covered, including global disease management, lupus nephritis and neuropsychiatric involvement, management of pregnancies, vaccinations and comorbidities monitoring. Unmet needs relate with disease management of some clinical manifestations and adherence to treatment. Many patient's unmet needs have been identified starting with faster diagnosis, need for more therapeutic options, guidelines on lifestyle issues, attention to quality of life and adequate education.

INTRODUCTION

Systemic lupus erythematosus (SLE) is the paradigm of systemic autoimmune diseases characterised by a wide spectrum of clinical manifestations with an unpredictable relapsing-remitting course. While paediatric cases are described, SLE typically affects women between 16 years and 55 years. It is a heterogeneous condition, which may involve almost all organs and tissues. Some of the most common clinical features are mucocutaneous lesions, arthritis, renal involvement, haematological disorders, serositis and fever. Forty per cent to 70% of SLE patients suffer from lupus nephritis (LN) whose dominant feature is proteinuria usually associated with urinary

Key messages**What is already known about this subject?**

- Systemic lupus erythematosus (SLE) is the paradigm of systemic autoimmune diseases characterised by a wide spectrum of clinical manifestations with an unpredictable relapsing-remitting course.
- A good number of Clinical Practice Guidelines are currently available on SLE.

What does this study add?

- This review represents a state of the art on existing Clinical Practice Guidelines and unmet needs in SLE.

How might this impact on clinical practice?

- In the framework of the European Reference Network on Rare and Complex Connective Tissue and Musculoskeletal Diseases (ERN ReCONNET), clinicians and patients will collaborate closely to address the unmet needs identified with the aim of harmonising the care provided to SLE patients.

sediment abnormalities. Between 10% and 20% of patients with LN will develop chronic renal failure. Neuropsychiatric manifestations can also occur such as severe headache, seizure disorder, psychosis, acute confusional state and cognitive dysfunction. A higher rate of mortality and morbidity is associated with renal and neuropsychiatric involvements. The serological picture of SLE is characterised by the positivity of many autoantibodies among which the most specific are anti-dsDNA and anti-Sm. The presence of antiphospholipid antibodies is associated with a worse prognosis. During the course of SLE, patients may accrue both disease-related

and treatment-related damage. Although better use of available therapies has greatly improved outcome, SLE is still associated with a significant morbidity. In view of the large amount of specialists potentially involved in the daily care of SLE patients, as well as the various therapeutic approaches, it is important to establish a commonly shared treatment strategy. Clinical practice guidelines (CPGs) are systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances.¹ CPGs have been proposed for SLE, but they are sparse and not homogeneous. This manuscript intended is aimed at identifying current available CPGs for SLE and physician's and patients' unmet needs.

METHODS

ERN Rare CONnective tissue and musculoskeletal diseases NETWORK (ReCONNET) SLE core set network

ERN ReCONNET is a European Reference Network funded by the European Union's Health Program to promote better and safer healthcare, define proper organisational assessment and identify standard and cost-effective pathways for the management of Rare and Complex Connective Tissue Diseases. The network includes rheumatologists (adult and paediatric), internists and immunologists from 26 selected centres in eight different countries across Europe.

Within the ERN ReCONNET, the SLE core set network is composed of the members of the network involved in SLE, of FT and NC-C (the official SLE Disease Coordinators, junior and senior) and of two methodologists of the ERN ReCONNET.

The SLE core set network is addressed to focus on the management of all forms of SLE disease manifestations, including rare and complex conditions.

One of the first core set network targets was to identify the currently available CPGs pertaining to SLE, in order to identify potential unmet needs, which should be further focused on. A literature search included all the papers published until July 2017. Analysis was conducted between June 2017 and February 2018. Planning and evaluation of the work was driven by regular interactions between participants of the working group during meetings (European League Against Rheumatism - EULAR congress 2017, American College of Rheumatology -ACR congress 2017, ERN ReCONNET meeting in Pisa, 4-6 of February 2018), web conferences, emails and the ERN Collaborative Platform (<https://webgate.ec.europa.eu>).

Systematic literature search

We carried out a systematic search in PubMed and Embase based on controlled terms (MeSH and Emtree) and keywords and on publication type (CPGs), in order to identify existing CPGs on diagnosis, monitoring and treatment, according to the Institute of Medicine 2011 definition: *clinical practice guidelines are statements that include recommendations intended to optimise patient care that*

are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.

The search strategy is: MEDLINE (PubMed): ('lupus erythematosus, systemic'[MeSH Terms] OR ('lupus'[All Fields] AND 'erythematosus'[All Fields] AND 'systemic'[All Fields])) OR 'systemic lupus erythematosus'[All Fields] OR ('systemic'[All Fields] AND 'lupus'[All Fields] AND 'erythematosus'[All Fields])) AND ('Practice Guideline'[Publication Type] OR 'Practice Guidelines As Topic'[MeSH Terms] OR Practice Guideline [Publication Type] OR 'Practice Guideline'[Text Word] OR 'Practice Guidelines'[Text Word] OR 'Guideline'[Publication Type] OR 'Guidelines As Topic'[MeSH Terms] OR Guideline[Publication Type] OR 'Guideline'[Text Word] OR 'Guidelines'[Text Word] OR 'Consensus Development Conference'[Publication Type] OR 'Consensus Development Conferences As Topic'[MeSH Terms] OR 'Consensus'[MeSH Terms] OR 'Consensus'[Text Word] OR 'Recommendation'[Text Word] OR 'Recommendations'[Text Word] OR 'Best Practice'[Text Word] OR 'Best Practices'[Text Word]). Embase: ('lupus erythematosus'/exp OR 'chronic lupus erythematosus' OR 'lupus erythematoses' OR 'lupus erythematosus' OR 'lupus erythematosus' OR 'lupus erythematosus treatment' OR 'lupus syndrome') AND ('practice guideline'/exp OR 'practice guideline' OR 'practice guidelines'/exp OR 'practice guidelines' OR 'clinical practice guideline'/exp OR 'clinical practice guideline' OR 'clinical practice guidelines'/exp OR 'clinical practice guidelines as topic'/exp OR 'clinical practice guidelines as topic' OR 'guideline'/exp OR 'guideline' OR 'guidelines'/exp OR 'guidelines' OR 'guidelines as topic'/exp OR 'guidelines as topic' OR 'consensus development'/exp OR 'consensus development' OR 'consensus development conference'/exp OR 'consensus development conference' OR 'consensus development conferences'/exp OR 'consensus development conferences' OR 'consensus development conferences as topic'/exp OR 'consensus development conferences as topic' OR 'consensus'/exp OR 'consensus' OR 'recommendation' OR 'recommendations') AND [embase]/lim NOT [medline]/lim.

In order to implement the list of guidelines provided by MEDLINE and Embase search, the group also performed a hand search.

Methodology of CPGs identification

All references included in the final list (systematic search+hand search) identified during the systematic literature search were screened for eligibility by two evaluators, the Disease Coordinators (NC-C and FT) of the ERN ReCONNET for SLE, based on title and abstract assessment. We addressed the following question: does this paper describe CPG? Manuscripts scored as such by at least one of the two evaluators were included in the next step.

The two evaluators then assessed all selected references with the full article in order to confirm that they were

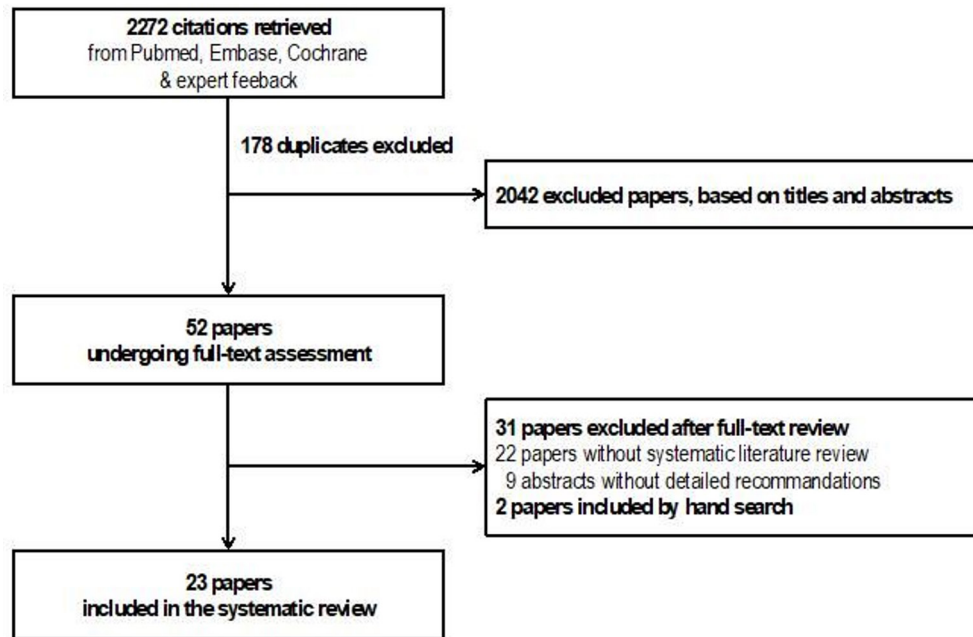


Figure 1 Flowchart constructed from Pubmed, Embase, and national databases.

CPGs. In case of no agreement, a further round of discussion involving a third evaluator (LA) was performed, in order to reach consensus.

A discussion group was set up to confirm inclusion and evaluation of the selected CPGs. The topics covered by each guideline were systematically evaluated by one member of the group (FF) in order to guide the discussion group during the identification of the unmet needs. Physician's unmet needs were then defined by the group, each participant giving his thoughts regarding what is not currently addressed by the current guidelines.

Finally, the patient's unmet needs paragraph intends to highlight the unmet needs of the European lupus community. The content of this paragraph has been realised by the ERN ReCONNET European Patient Advocacy Group that carefully collected the voices and the points of view of the whole European community of the disease they represent by means of meetings and web conferences.

RESULTS

State of the art on CPGs

Identification of existing CPGs

The systematic literature search yielded a total of 2272 citations. Title and abstract evaluation identified 52 papers suitable for full-text review. After full-text review, 21 original guidelines were identified²⁻²³ (figure 1) (figure 1). Of note, Saavedra *et al* published one guideline, which is divided into two parts with two different references, but this guideline was counted as one in the systematic search.^{15 16} Two articles were included by hand search,^{24 25} leading to a total of 23 CPGs.

The general characteristics of the 23 CPGs are summarised in table 1. Twenty-one were in English

(including one in both English and Portuguese⁸) and two in French. Sixteen guidelines had been endorsed/supported by an official society or organisation: European League Against Rheumatism (EULAR) (n=8), American College of Rheumatology (ACR) (n=3), Brazilian Society of Rheumatology (n=1), European Union (SHARE initiative) (n=2), Mexican College of Rheumatology (n=1) and Italian Society of Laboratory Medicine (n=1). The guidelines were published between 2004 and 2017 with only four published before 2010.

Five CPGs involved patient representatives and one involved a patient panel. Fifteen CPGs were dedicated to SLE, while eight covered a broader spectrum of rheumatic diseases (including SLE). Seventeen targeted all patients (juvenile and adult), four papers specifically targeted juvenile SLE and two female SLE. Five CPGs addressed general management of SLE, five addressed prevention or treatment of infections (three specifically focusing on vaccination), four focused on a specific SLE organ involvement (three on renal disease and one on neuropsychiatric disease) two addressed immunologic laboratory testing, while others focused on pregnancy and family planning (n=2), cardiovascular risk management (n=2), cancer (n=1), orthopaedic perioperative management (n=1) or fatigue (n=1).

UNMET NEEDS

Clinicians' unmet needs

This review provides an overview of currently available CPGs for SLE. Yet, there are several areas that are not (yet) covered by guidelines.

The following items were considered as correctly covered: (1) global management of SLE,^{5 10 14 20 22} including a treat-to-target strategy²²; (2) autoantibodies testing^{4 19}; (3)

Table 1 CPGs general characteristics

Author	Endorsement by	Language other than English	Date	Target	Scope	Patients' representatives
Andreoli <i>et al</i> ²	EULAR		2017	Women with SLE	Family planning, pregnancy, menopause in SLE and APS.	Yes (n=2)
Arnaud <i>et al</i> ³	/	French	2015	All patients with SLE	Cardiovascular risk management in SLE.	No
Benito-Garcia <i>et al</i> ⁴	ACR		2004	Patients with rheumatic diseases	Immunological laboratory testing.	No
Bertsias <i>et al</i> ⁵	EULAR		2008	All patients with SLE	General management of SLE.	No
Bertsias <i>et al</i> ⁶	EULAR		2010	All patients with SLE	Neuropsychiatric disease.	Yes (n=1)
Bertsias <i>et al</i> ⁷	EULAR		2012	All patients with SLE	Renal disease.	Yes (n=1)
Braz <i>et al</i> ⁸	Brazilian Society of Rheumatology	English and Portuguese	2015	Patients with autoimmune rheumatic diseases	Diagnosis and treatment of intestinal parasitic infections.	No
Goodman <i>et al</i> ⁹	ACR		2017	Patients with rheumatic diseases	Perioperative management of antirheumatic medication in patients undergoing elective total hip or total knee arthroplasty.	Yes (patients' panel)
Groot <i>et al</i> ¹⁰	EU (SHARE initiative)		2017	Juvenile SLE	General management of childhood-onset SLE.	No
Hahn <i>et al</i> ¹¹	ACR		2012	All patients with SLE	Renal disease.	No
Heijstek <i>et al</i> ¹²	EULAR		2011	Pediatric patients with rheumatic diseases	Vaccinations.	No
Mathian <i>et al</i> ¹³	/	French	2016	All patients with SLE	Prevention of infections.	No
Mosca <i>et al</i> ¹⁴	EULAR		2010	All patients with SLE	General management of SLE.	No
Savreeda Salinas part 1 ¹⁵ and 2 ¹⁶	Mexican College of Rheumatology		2015	Women with autoimmune rheumatic diseases	Management of pregnancy.	No
Silva <i>et al</i> ¹⁷	/		2009	Children and adolescents with rheumatic diseases	Vaccinations.	No
Tessier-Cloutier <i>et al</i> ¹⁸	/		2015	All patients with SLE	Monitoring of malignancies.	No
Tozzoli, <i>et al</i> ¹⁹	Italian Society of Laboratory Medicine		2002	Autoimmune rheumatic diseases	Laboratory use of autoantibody tests.	No
Trujillo-Martin, <i>et al</i> ²⁰	/		2016	All SLE patients	General management.	Yes (n=1)
Tselios, <i>et al</i> ²¹	/		2015	All SLE patients	Cardiovascular risk management.	No
Van Vollenhoven, <i>et al</i> ²²	EULAR		2014	All SLE patients	General management (treat to target).	Yes (n=1)
Yuen ²³	/		2014	All SLE patients	Fatigue.	No
Groot, <i>et al</i> ²⁴	EU (SHARE initiative)		2017	Juvenile SLE with renal involvement	Management of childhood-onset SLE nephritis.	No
van Assen, <i>et al</i> ²⁵	EULAR		2011	Rheumatic diseases	Vaccinations.	No

APS, Antiphospholipid syndrome ; CPGs, clinical practice guidelines; SLE, systemic lupus erythematosus.

management of fatigue²³; (4) monitoring for malignancies¹⁸; Screening and management of cardiovascular risk factors³ and coronary disease risk monitoring²¹; (5) management (including treatment) of the two most severe manifestations of SLE, namely lupus nephritis^{7 11} (including in children²⁴) and neuropsychiatric involvement⁶; (6) prevention of infections¹³ with a focus on intestinal parasitic infections⁸; (7) vaccination in adults,²⁵ in paediatric patients^{12 17} and in adolescents¹⁷; (8) pregnancy planning^{2 15 16} and management of menopause²; and (9) Perioperative management for hip and knee surgery.⁹

By contrast, several clinician's unmet needs were identified: (1) optimal management of serositis, gastrointestinal involvement, interstitial lung disease, retinal vasculitis, limited cutaneous disease, headaches and/or severe lymphopenia that are not covered by the current available CPGs. (2) Evaluation and management of non-adherence to treatment is a crucial missing point which is only addressed by one available CPG.¹⁰ (3) Optimal duration of immunosuppression, which is only partly addressed in some guidelines. (4) Patient's input on CPGs is missing. Only one CPG proposed patient assessment as a recommendation, which consisted in an evaluation of her/his quality of life by using a visual analogue scale.¹⁴ (5) Except one CPG on LN,¹¹ none of the available CPGs addressed the important question of ethnicity and its possible impact on disease severity. (6) No definition of photosensitivity and vasculitis is provided in current CPGs. (7) No mention of non-health related prognostic determinants, such as patients' socioeconomic status.

Patients' unmet needs

The first unmet need identified by patients deals with delay and uncertainty in diagnosis until confirmation by a specialist. This adds to the psychological burden of the disease, which might be aggravated if treatment is delayed. The need for new treatment options, less reliant on steroids and associated with fewer side effects, is a high priority for patients. They advocate a more holistic disease management, going beyond specific symptoms or an 'organ by organ' management, to include a global treatment plan, coordinated by one physician, in casu a lupus expert, who treat them as a 'full person' and takes care, besides the clinical aspects, of the psychological issues. In our working group meetings, lupus patients defined treatment as "any product or activity aiming at improving quality of life", clearly pinpointing the importance of a holistic approach. Patients are looking for scientifically validated patient focused guidelines on lifestyle issues. Research should be conducted jointly by HCPs and patient organisations to identify behaviours or actions that can help patients take day-to-day ownership of their treatment, understanding what to do, or not to do, based on hard data. Even if remission of SLE disease activity has been achieved, many patients still face pain and fatigue. Understanding the drivers would allow building treatment guidelines for those conditions, which is critical to avoid that people facing these symptoms are pushed prematurely out of the labour market. Finally, while a huge amount of information is available to patients on the web, this information

is of very low quality, often counterproductive and anxiety generating. There is a need for high-quality therapeutic patient education and for an efficacious way to fight fake news that spread over the internet, for example, by quality certified information, or diffusion of ERN-endorsed recommendations *via* social media posts.

CONCLUSIONS

Here we proposed an overview of the current available CPGs on SLE. Many unmet needs have been identified. Soon after we performed the systematic research, two clinical guidelines have been published.^{26 27} Gordon *et al* published the British guideline on SLE,²⁶ which proposed recommendations for some of these unmet needs, such as patient reported outcomes (Short Form (SF)-36 and Lupus QoL indices) and for immunosuppression duration. Pons-Estel *et al*²⁷ published another guideline with a focus on socio-economic and ethnic—namely in Latin Americans—aspects. Yet, many areas remain uncovered, and efforts are still needed to improve and standardise our daily practice.

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