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Development of quality indicators to evaluate the monitoring of SLE patients in routine clinical practice

M. Mosca[a,*], **C. Tani**[a], **M. Aringer**[b], **S. Bombardieri**[a], **D. Boumpas**[c], **R. Cervera**[d], **A. Doria**[e], **D. Jayne**[f], **M. A. Khamashta**[g], **A. Kuhn**[h], **C. Gordon**[i], **M. Petri**[j], **M. Schneider**[k], **Y. Shoenfeld**[l], **J. S. Smolen**[m], **R. Talarico**[a], **A. Tincani**[n], **M. M. Ward**[o], **V. P. Werth**[p], and **L. Carmona**[q]

[a]Rheumatology Unit, Department of Internal Medicine, University of Pisa, Pisa, Italy

[b]University Clinical Center Carl Gustav Carus at the Technical University of Dresden, Germany

[c]University of Crete Medical School, Heraklion, Crete, Greece

[d]Department of Autoimmune Diseases, Hospital Clinic, Barcelona, Catalonia, Spain

[e]Division of Rheumatology, University of Padova, Padova, Italy

[f]Renal Unit, Addenbrooke's Hospital, Cambridge, UK

[g]Lupus Research Unit, Rayne Institute, St Thomas Hospital, London, UK

[h]Department of Dermatology, University of Muenster, Muenster, Germany

[i]School of Immunity & Infection, University of Birmingham, UK

[j]Division of Rheumatology, Johns Hopkins University School of Medicine, Baltimore, MD, USA

[k]Rheumatology, Clinic of Endocrinology, Diabetology and Rheumatology, Heinrich-Heine-University, Duesseldorf, Germany

[l]Department of Medicine B and Center of Autoimmune Diseases, Sheba Medical Center, Tel Hashomer, Sackler Faculty of Medicine and Zabludowitcz Center for Autoimmunity Tel Aviv University, Tel Aviv, Israel

[m]Department of Rheumatology, Medical University of Vienna, Austria

[n]UO Reumatologia e Immunologia Clinica, Spedali Civili e Università, Brescia, Italy

[o]Intramural Research Program, National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH, US Department of Health and Human Services, Bethesda, MD, USA

[p]University of Pennsylvania, Philadelphia, PA, USA

[q]Research Unit, Fundacion Espanola de Reumatologia, Madrid, Spain

Abstract

The assessment of systemic lupus erythematosus (SLE) patients in routine clinical practice is mainly based on the experience of the treating physician. This carries the risk of unwanted

*Corresponding author: marta.mosca@int.med.unipi.it (M. Mosca).

variability. Variability may have an impact on the quality of care offered to SLE patients, thereby affecting outcomes. Recommendations represent systematically developed statements to help practitioners in reducing variability. However, major difficulties arise in the application of recommendations into clinical practice. In this respect, the use of quality indicators may raise the awareness among rheumatologists regarding potential deficiencies in services and improve the quality of health care.

The aim of this study was to develop a set of quality indicators (QI) for SLE by translating into QIs the recently developed *EULAR Recommendations for monitoring SLE patients in routine clinical practice and observational studies*.

Eleven QIs have been developed referring to the use of validated activity and damage indices in routine clinical practice, general evaluation of drug toxicity, evaluation of comorbidities, eye evaluation, laboratory assessment, evaluation of the presence of chronic viral infections, documentation of vaccination and of antibody testing at baseline. A disease specific set of quality assessment tools should help physicians deliver high quality of care across populations. Routine updates will be needed.

Keywords

Quality indicators; Quality of care; Systemic lupus erythematosus; Routine clinical practice

1. Introduction

The assessment of SLE patients in routine clinical practice is affected by the experience of the treating physician. Differences in experience and training will lead to significant variability [1,2]. Variability may have an impact on the quality of care offered to patients and ultimately influence outcomes. Recommendations represent systematically developed statements to support practitioners and patients to make decisions in specific clinical circumstances and essentially define best practice. Recommendations could help the physician in reducing variability of treatment approaches and pointing toward consensually developed therapeutic options. However, difficulties can arise in the application of recommendations into clinical practice, which may be explained largely by the gaps between recommendations and routine practice [3–6].

Quality indicators (QI) represent the minimal standard of care that should be provided to patients and may represent a practical guide to physicians on steps to further improve the quality of care offered to patients [7–16]. In addition, the translation of guidelines/recommendations into QIs could increase awareness of the existing guidelines and reduce the gap between guidelines and clinical practice. Their subsequent use to describe the minimal percentage of assessed patients at each center that would be considered a good compliance, still needs to be defined.

Recently a quality indicators set for SLE has been published, covering a number of aspects of patient's assessment [17]. The aim of this study was to develop a set of QIs for SLE by translating the recently developed *EULAR Recommendations for monitoring SLE patients in routine clinical practice and observational studies* [18] into QIs.

2. Methods

The procedure used to develop the QIs was based on the work done for the development of the EULAR recommendations. In brief, the following techniques were applied: nominal group, Delphi surveys for prioritisation, small group discussion, systematic literature review (SLR), and two rounds of Delphi technique for agreement [3,18].

Subsequently, a preliminary list of QIs was developed, based on the EULAR Recommendations.

A Delphi survey was then carried between the panel of experts who had originally taken part to the development of the EULAR Recommendations to assess priority, definitions and feasibility.

Indicators given a low priority were excluded, changes in definitions were made according with the opinions of the participating experts and the final set of QIs was prepared.

3. Results

A preliminary set of 15 QIs was developed which included the following: use of validated activity and damage indices in daily practice; assessment of quality of life, drug toxicity and comorbidities in daily practice; screening for cervical intraepithelial neoplasm (CIN), breast cancer and colorectal cancer; ophthalmologic assessment in patients treated with hydroxychloroquine and glucocorticoids; patients monitoring, evaluation for the presence of chronic viral infections, documentation of vaccination and of antibody testing at baseline.

Four QIs of the initial set were excluded as they were considered not relevant to rheumatology practice. QIs related to cancer screening were excluded, because of the low availability of such information to the rheumatologist and the fact that cancer screening is mainly performed by the general practitioner or other specialists.

The QI related to frequency of assessment was also excluded, as being extremely difficult to evaluate. In addition, it appeared difficult to discriminate between poor adherence to visits and change of referrals.

Eleven QIs were developed and are reported below (ref 18 for systematic literature review references).

QI 1. Use of validated activity indices in daily practice

IF a patient is diagnosed with SLE, THEN the treating physician should assess and record disease activity using a validated index at each visit.

Why it is important. The assessment of activity has important prognostic significance, as a significant correlation between the degree of activity and damage accrual has been shown. Although the assessment of activity is part of the routine clinical evaluation, it relies on the physician’s experience and, therefore, may be subject to significant inter-and intra-rater variability. The use of validated indices should greatly improve the collection of data, and,

therefore, the quality, of the assessment made during routine evaluations. Unfortunately it is feasible to perform validated disease activity indices in routine clinical practice.

Descriptors for this QI are reported in Table 1. In the evaluation of the adherence to this QI it is important to remember that at first assessment, data needed to evaluate disease activity might be lacking and the patient may require further evaluation. Therefore, the first visit after diagnosis is confirmed should be considered in the count.

QI 2. Use of validated damage index in daily practice

IF a patient is diagnosed with SLE, THEN the treating physician should assess and record disease damage by the SLICC/ACR damage index annually.

Why it is important. Damage assessment has an important prognostic significance as studies have shown a significant correlation between early damage accrual and the development of additional damage and mortality. The Systemic Lupus International Collaborating Clinics (SLICC/ACR) Damage Index has been developed to assess irreversible damage in SLE patients occurring after disease onset, regardless of attribution.

Indeed, the assessment of damage should be part of the routine clinical evaluation. However, it relies on the physician's experience and therefore may be subject to significant inter- and intra-rater variability. The use of validated indices should greatly improve the collection of data, and therefore the quality, of the assessment made during routine evaluations. A yearly assessment of the SLICC/ACR has, therefore, been suggested in the recently published Recommendations.

Descriptors for this QI are reported in Table 1. In the evaluation of the adherence to this QI it is important to remember that, at the first assessment, data needed to evaluate disease damage might be lacking and the patient may require further evaluation. Therefore, the first visit after diagnosis is confirmed should be considered in the count.

QI 3. Assessment of quality of life in daily practice

IF a patient is diagnosed with SLE, THEN he/she should provide an evaluation of his/her quality of life at each visit.

Why it is important. Many studies have documented poor correlations between activity and damage versus quality of life, suggesting that these measures assess different aspects of patient status. In randomized controlled trials, the assessment of quality of life is usually based on the use of the short form 36 (SF36). Recently, SLE-specific indices have also been developed. As their use in clinical practice is not yet routinary, the evaluation of the patient's quality of life can be based on the patient's history, on a 0 to 10 VAS (patient global), as well as on the use of validated indices. Descriptors for this QI are reported in Table 1.

QI 4. Assessment of drug toxicity in daily practice

IF a patient is diagnosed with SLE, THEN the treating physician should assess the presence of drug toxicity at each visit, and record the data in the clinical chart. Alternatively, the physician should record the absence of drug toxicity.

Why it is important. The clinical picture of SLE patients is extremely variable and may be related to disease activity, organ damage, drug toxicity and quality of life. It is part of standard care to evaluate whether patients have side effects to drugs, and whether drug toxicity affects patient outcomes or requires additional monitoring.

Although the absence of any mention of side effects and of any change in medication could be interpreted as “no side effects”, this information should be regularly recorded in the clinical chart. This requirement could help in collecting information that otherwise may be overlooked.

This could be achieved either by providing a list of possible side effects which might be too cumbersome for the use in routine clinical practice. It could be simply done by reporting in the chart “drug side effects: present/absent”, followed by a specification of the observed abnormalities. Descriptors for this QI are reported in Table 1.

QI 5. Assessment of comorbidities in daily practice

IF a patient is diagnosed with SLE, THEN the treating physician or a specialized nurse should record the presence of comorbid conditions at least once a year.

Why it is important. SLE patients are at increased risk of comorbidities, including cardiovascular risk factors, osteoporosis and cancer. These have an impact on damage development, morbidity and mortality and require appropriate prevention or therapy. Comorbidities can change over time in relation to patients ageing, medication, or disease evolution. Therefore their presence should be updated regularly.

A list of the more frequent comorbidities observed among SLE patients may help the physician in this assessment and could become a part of the clinical record (Table 2). The absence of any comorbidity should also be recorded.

QI 6. Ophthalmologic assessment in patients treated with hydroxychloroquine

If a patient is diagnosed with SLE and treated with hydoxycloroquine/chloroquine, THEN he/she should undergo an ophthalmologic assessment according with the existing guidelines and this should be documented in the clinical chart.

Why it is important. Hydroxychloroquine, and less frequently choloroquine, are largely used in the treatment of SLE patients.

Although rare, ocular toxicity is the major limitation to the use of these drugs. In very initial stages of toxicity, cessation of the drug may result in a reversal of toxicity. On the other side, if the drug is not withdrawn, there might be irreversible loss of visual acuity.

Risk factors for the development of retinal toxicity have been identified and include age (above 60 years), presence of macular degeneration, retinal dystrophy, obesity, liver disease, renal insufficiency, duration of therapy over 5 years, daily dose of hydroxychloroquine above 6.5 mg/kg ideal body weight/per day, or chloroquine above 4 mg/kg ideal body weight per/day.

In addition, in all cases of possible increased risk, the decision to continue therapy and at what dose is a matter for discussion and will depend on comorbidities, as stopping hydroxychloroquine and having to increase corticosteroids may increase the risk of greater side effects. Discussion on the assessment of possible ocular toxicity should include also ophthalmologists.

Monitoring for the presence of early retinal damage is, therefore, very important for the prevention of irreversible damage.

QI 7. Ophthalmologic assessment in patients treated with glucocorticoids

If a patient is diagnosed with SLE and treated with corticosteroids, THEN he/she should undergo an ophthalmologic assessment for the presence of cataracts and glaucoma according to the existing guidelines. This should be documented in the clinical chart.

Why it is important. Drug-induced subcapsular cataracts occur among patients treated with glucocorticoids. Data available on SLE patients confirm a significant association between cumulative prednisone dose (36.5 g) and later development of cataracts with a RR: 1.9 (CI 1.4–2.5).

Systemic glucocorticoids also increase the risk of glaucoma by raising the intraocular pressure. Risk factors for glaucoma development are a family history of glaucoma, age (over 40 years), ethnic background (African-Americans are six to eight times more likely to develop glaucoma than are Caucasians), diabetes mellitus, hypertension, hypothyroidism, great myopia, pre-existing glaucoma, chronic uveitis, and iritis.

The EULAR evidence-based recommendations on the management of systemic glucocorticoid therapy in rheumatic diseases indicate cataract or glaucoma as comorbidities, based on a level of evidence of IV (expert committee reports/opinions and/or clinical opinion of respected authorities) and a strength of recommendation of 92 (CI: 87–96).

QI 8. Patient monitoring — laboratory assessment

IF a patient is diagnosed with SLE, THEN at least every six months, the rheumatologist should request the following laboratory assessment: complete blood count, erythrocyte sedimentation rate, albumin, serum creatinine or e-GFR, urinalysis and protein/creatinine ratio (or 24 h proteinuria), C3 and C4.

Why it is important. Severe anaemia has been variably associated with organ involvement (kidney), disease progression (end stage renal disease) and prognosis (survival). Similarly, thrombocytopenia has been associated with anti-phospholipid antibodies, renal disease, disease progression to end-stage renal disease and prognosis (worse outcome/survival).

Leucocytopenias have been associated with the occurrence of infections. Lymphopenia is associated with disease activity and infections. Serum albumin, creatinine, urinalysis, urine protein/creatinine ratio and blood pressure provide information on the presence and prognosis of renal involvement.

Erythrocyte sedimentation rate (ESR) has been associated in some studies with active disease, although no univocal data are available in this respect. It has been included in this QI based on the low cost of the test and the potential utility in clinical practice. Complement levels are sometimes associated with active disease. Low complement levels may help in diagnosing a disease flare, although no predictive value for the development of disease flares has been shown.

QI 9. Infection risk. Screening for the presence of chronic infections

If a patient is diagnosed with SLE and is prescribed high dose corticosteroids or immunosuppressive drugs, THEN, based on the patient's history, the rheumatologist should consider the evaluation of hepatitis C virus (HCV), hepatitis B virus (HBV), and tuberculosis screening and record the results into the clinical chart before starting therapy.

Why it is important. Infection represents one leading cause of death in SLE patients. Occurrence of infections has been related both to immunosuppressive therapy and the disease itself. Most severe infections are newly acquired, and routine testing for chronic infections is not recommended. However, in view of the risks of occurrence and reactivation of chronic infections following IS therapy, and with glucocorticoids in particular, patients should be screened for tuberculosis, HCV and HBV infections before administering high dose glucocorticoids or any other IS medications. In patients with SLE, anergy, particularly in association with glucocorticoids therapy, may occur. Therefore, alternative screening methods (chest radiographs) should also be considered in PPD negative patients. Screening for other chronic infections should also be considered after careful assessment based on individual risk factors.

QI 10. Documentation of vaccination

If a patient is diagnosed with SLE, THEN the patient's history of vaccinations should be documented. Patients should be vaccinated against influenza and pneumococcus (preferably without adjuvant), if there are no contraindication to immunization.

Why it is important. SLE patients are at an increased risk of severe disease course and death following influenza or pneumonia. Indeed, infections are a major cause of death in SLE. Because of earlier concerns that disease flares were likely to be triggered by vaccination, many SLE patients are still not appropriately vaccinated and thus inadequately protected. It is now clear that non-live vaccination do not pose a significant risk to a patient. Vaccination against influenza and pneumococcus is effective in most SLE patients. Although vaccination is under the charge of general practitioners in most countries, rheumatologists should be aware of the vaccination status of their patients, and advise the GP accordingly.

QI 11. Documentation of antibody testing at baseline

If a patient is diagnosed with SLE, THEN the following autoantibodies should be evaluated at the first evaluation: ANA, anti-dsDNA, anti-Ro, anti-La, anti-RNP, anti-Sm, anti-phospholipid.

Why it is important. The autoantibody profile can help to predict clustering of symptoms and signs of SLE. This assessment has both diagnostic and prognostic importance. Since ANA and other auto-antibodies are included in the ACR Classification Criteria, autoantibody determination is part of the basic diagnostic evaluation of SLE patients. In addition, changes in anti-dsDNA antibody titers may be helpful in monitoring disease activity. Anti-Ro, anti-La and anti-ribonucleoprotein (RNP) antibodies may have prognostic value in SLE. Anti-Ro and anti-La are associated with cutaneous lupus and with Sjögren syndrome and congenital heart block Anti-phospholipid (aPL) antibodies have been associated with thrombotic manifestations, pregnancy losses and damage development.

4. Discussion

The assessment of standard of care is increasingly relevant, as it represents a way to monitor whether appropriate care is given to patients. It could impact on patient treatment, as well as on appropriate allocation of health care resources. Assessing quality could improve patient outcomes, by promoting best practices among physicians [3–17].

Quality indicators (QI) represent markers for compliance with minimal standards of care. They are not meant to represent the best practice or to replace guidelines for patient management. Rather, QIs, which are developed on the basis of guidelines or recommendations, may help reduce the existing gap between guidelines and clinical practice [4]. Thus QIs offer a tool for assessing health care quality and should be based on strong scientific evidence [7–10].

In the present study, we have developed a set of 11 QIs based on recently developed EULAR Recommendations which combine data from a systematic literature review with expert opinion [18]. We hope that these QIs will serve as beacons to improve clinical practice.

Some limitations of these QIs are recognized. First of all, the correct evaluation of QIs requires high quality medical records. Missing data may either reflect the absence of a specific manifestation or alternatively, that appropriate history or examination was not performed or not documented. As an example for the latter, the absence of side effects might not be recorded in the chart, despite having been explicitly investigated in the visit. To help overcome the problem of recording comorbidities and toxicities, specific lists can be inserted into clinical charts, such as the one proposed in Table 2 of the present manuscript.

QIs can also not take into consideration that differing guidelines may be available in different countries, for example with reference to ophthalmologic assessment. Also, patients may visit their ophthalmologist independently of their rheumatologist. Nevertheless, we think that rheumatologists, who take the responsibility for prescribing the drugs, should also record the results of such examinations.

Finally, the frequency of some assessments may vary, based on different patients characteristics and clinical manifestations. This aspect needs to be assessed after an initial application of the QIs and variations for different patients subgroups (i.e. with or without nephritis) might be required.

In conclusion, in the present paper we propose a list of QIs that could serve to implement and assess compliance with EULAR Recommendations for SLE in routine clinical practice [18]. We hope that these QIs will help to further improve the quality of patient care, as well as to translate recommendations into clinical practice.

Their subsequent use to establish the numeric cut off that properly defines good clinical practice – e.g. that at least 70% of patients with SLE at each center should be screened for the presence of chronic infections – still needs to be discussed and will be the subject of future studies. In addition, measures of quality of care could be seen in success or failure rates when caring for patients with SLE, such as the proportion of patients with lupus nephritis who do not develop endstage renal disease; however, the complexity of such analyses (such as, for example, the additional role of patients compliance) makes this aspect also be part of a research agenda.

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Take-home messages

- A patient assessment based on the experience of the treating physician carries the risk of unwanted variability.
- Variability may have an impact on the quality of care.
- Quality indicators (QIs) represent the minimal standard of care that should be provided to patients.
- Quality indicators (QIs) represent the minimal standard of care that should be provided to patients.
- The use of QIs to establish the numeric cut off that properly defines good clinical practice still needs to be discussed.

Table 1

Quality indicators proposed for the monitoring of lupus patients I agree with comment to avoid repetition in statements.

	Quality indicator (QI)	Description	Who measures it?	When is it measured?	Where does the data come from?
QI 1	*IF a patient is diagnosed with SLE, THEN the treating physician should assess and record disease activity using a validated index at each visit.*	% of total SLE patients registered in a unit (service, department, clinic) in whom a validated activity index is used at each visit with a physician	TPhy, RS, HM/EAu	Y or at specific CSAu	CR[a]
QI 2	*IF a patient is diagnosed with SLE, THEN the treating physician should assess and record disease damage by the SLICC/ACR damage index annually.*	% of total patients registered in a Unit (service, department, clinic) in whom a the Systemic Lupus International Collaborating Clinics (SLICC/ACR) damage index is used once a year	TPhy, RS, HM/EAu	Y or at specific CSAu	CR[a]
QI 3	*IF a patient is diagnosed with SLE, THEN he/she should provide an evaluation of his/hers quality of life at each visit.*	% of patients to whom is asked a judgment on their quality of life either on a visual analogue scale from 0 to 10 or using any validated index (SF36, SLE-QoL)	TPhy, RS, HM/EAu	Y or at specific CSAu	CR[a]
QI 4	*IF a patient is diagnosed with SLE, THEN the treating physician should assess the presence of drug toxicity at each visit, and record the data in the clinical chart. Alternatively, the physician should record the absence of drug toxicity.*	% of SLE patients for whom the presence/absence of side effects from drugs is reported in clinical charts at each visit	TPhy, RS, HM/EAu	Y or at specific CSAu	CR[a]
QI 5	*IF a patient is diagnosed with SLE, THEN the treating physician or a specialized nurse should record the presence of comorbid conditions at each visit.*	% of total patients for whom comorbidities are recorded in the clinical charts (Absence of comorbidities should be also recorded)	TPhy, RS, HM/EAu	Y or at specific CSAu	CR[a]
QI 6	*If a patient is diagnosed with SLE and treated with hydoxycloroquine/ chloroquine THEN he/she should undergo an ophthalmologic assessment according with the existing guidelines. and this should be documented in the clinical chart.*	% percentage of patients treated with HCQ and undergoing eye assessment	TPhy, RS, HM/EAu	Y or at specific CSAu	CR[a], Opticians, Ophtalmologist report
QI 7	*If a patient is diagnosed with SLE and treated with corticosteroids THEN he/she should undergo an ophthalmologic assessment for the presence of cataracts and/or glaucoma according with the existing guidelines. This should be documented in the clinical chart*	Percentage of patients treated with corticosteroids and undergoing eye assessment for the presence of cataracts/glaucoma	TPhy, RS, HM/EAu	Y or at specific CSAu	CR[a], Opticians, Ophtalmologist report
QI 8	*IF a patient is diagnosed with SLE THEN at least every six months the rheumatologist should request the following laboratory assessment: complete blood count, erythrocyte sedimentation rate, albumin, serum creatinine or e-GFR, urinalysis and protein/creatinine ratio (or 24 h proteinuria), C3 and C4*	Percentage of patients in whom the listed exams are performed at each assessment	TPhy, RS, HM/EAu	Y or at specific CSAu	CR[a]
QI 9	*If a patient is diagnosed with SLE and is prescribed high dose corticosteroids and/or immunosuppressive drugs THEN, based on patient's history, the rheumatologist should consider the evaluation of HCV, HBV and tuberculosis screening and record the results into the clinical chart before starting therapy*	Percentage of patients with SLE and treated with high dose corticosteroids and/or immunosuppressive drugs for whom the presence/ absence of chronic infectious diseases is documented	TPhy, RS, HM/EAu	Y or at specific CSAu	CR[a]
QI 10	*If a patient is diagnosed with SLE, THEN the patient's history of vaccinations should be documented. Patients should be vaccinated against influenza and pneumococcus (preferably without adjuvant), if there are no contraindication to immunization.*	Percentage of patients with SLE that receive vaccination against influenza and pneumococcus	TPhy, RS, HM/EAu	Y or at specific CSAu	CR[a]

	Quality indicator (QI)	Description	Who measures it?	When is it measured?	Where does the data come from?
QI 11	*If a patient is diagnosed with SLE, THEN the following autoantibodies should be evaluated at the first evaluation: ANA, anti-dsDNA, anti-Ro, anti-La, anti-RNP, anti-Sm, anti-phospholipid*	Percentage of patients with SLE that at initial assessment are evaluated for ANA, anti-dsDNA, anti-Ro, anti-La, anti-RNP, anti-Sm, anti-phospholipid	TPhy, RS, HM/EAu	Y or at specific CSAu	CR[a]

Abbreviations: SLE, systemic lupus erythematosus; TPhy, treating physician; RS, Rheumatology staff; HM/EAu, Hospital Management/External Auditor; Y, Yearly; CSAu, cross-sectional audits; CR, clinical records; HCQ, hydroxy-chloroquine; GFR, glomerular fraction rate, HCV, hepatitis C virus, HBV hepatitis B virus.

[a]Either paper or computerized.

Table 2

Checklist of the most frequent comorbidities observed among SLE patients.

Date of assessment	**Date of assessment**	**Date of assessment**
☐ No comorbidities	☐ No comorbidities	☐ No comorbidities
☐ Obesity	☐ Obesity	☐ Obesity
☐ Diabetes	☐ Diabetes	☐ Diabetes
☐ Smoking	☐ Smoking	☐ Smoking
☐ Hypertension	☐ Hypertension	☐ Hypertension
☐ Hyperlipidemia	☐ Hyperlipidemia	☐ Hyperlipidemia
☐ Cardiovascular disease (specify)	☐ Cardiovascular disease (specify)	☐ Cardiovascular disease (specify)
☐ Osteoporosis	☐ Osteoporosis	☐ Osteoporosis
☐ Cancer (specify)	☐ Cancer (specify)	☐ Cancer (specify)
☐ Chronic infection (specify)	☐ Chronic infection (specify)	☐ Chronic infection (specify)
☐ Thyroid disease	☐ Thyroid disease	☐ Thyroid disease
☐ Vitamin D deficiency	☐ Vitamin D deficiency	☐ Vitamin D deficiency