Development of American College of Rheumatology Quality Measures for Systemic Lupus Erythematosus: A Modified Delphi Process with RISE Registry Data Review

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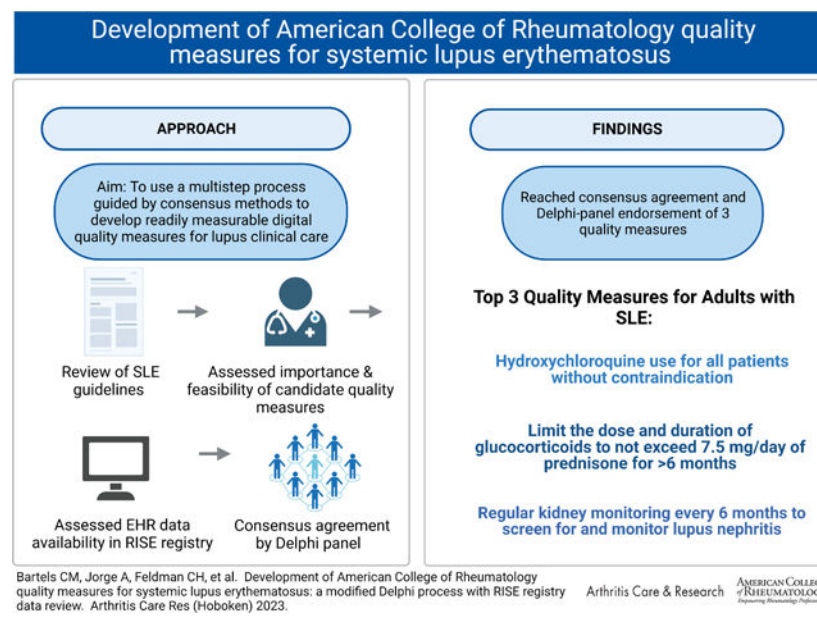
Abstract

Objective—We aimed to develop readily measurable digital quality measure statements for clinical care in systemic lupus erythematosus (SLE) using a multi-step process guided by consensus methods.

Methods—Using a modified Delphi process, an American College of Rheumatology (ACR) workgroup of SLE experts reviewed all North American and European guidelines from 2000–2020 on treatment, monitoring, and phenotyping of patients with lupus. Workgroup members extracted quality constructs from guidelines, rated these by importance and feasibility, and generated evidence-based quality measure statements. The ACR Rheumatology Informatics System for Effectiveness (RISE) registry was queried for measurement data availability. In three consecutive Delphi sessions, a multidisciplinary Delphi panel voted on importance and feasibility of each statement. Proposed measures with consensus on feasibility and importance were ranked to identify the top three measures.

Results—Review of guidelines and distillation of 57 quality constructs resulted in 15 quality measure statements. Among these, five met high consensus for importance and feasibility, including two on treatment and three laboratory monitoring measures. The three highest-ranked statements were recommended for further measure specification as SLE digital quality measures: 1) hydroxychloroquine use, 2) limiting glucocorticoid use >7.5 mg/day to <6 months, and 3) end-organ monitoring of kidney function and urine protein excretion at least every 6 months.

Conclusion—The Delphi process selected three quality measures for SLE care on hydroxychloroquine, glucocorticoid reduction and kidney monitoring. Next, measures will undergo specification and validity testing in RISE and US rheumatology practices as the foundation for national implementation and use in quality improvement programs.

Graphical abstract

Development of American College of Rheumatology quality measures for systemic lupus erythematosus

APPROACH

Aim: To use a multistep process guided by consensus methods to develop readily measurable digital quality measures for lupus clinical care

Review of SLE guidelines → Assessed importance & feasibility of candidate quality measures

Assessed EHR data availability in RISE registry → Consensus agreement by Delphi panel

FINDINGS

Reached consensus agreement and Delphi-panel endorsement of 3 quality measures

Top 3 Quality Measures for Adults with SLE:

Hydroxychloroquine use for all patients without contraindication

Limit the dose and duration of glucocorticoids to not exceed 7.5 mg/day of prednisone for >6 months

Regular kidney monitoring every 6 months to screen for and monitor lupus nephritis

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INTRODUCTION

Systemic lupus erythematosus (SLE) is a chronic autoimmune disease associated with significant morbidity and premature mortality. Studies have characterized numerous disparities in health care access and quality among people with SLE.[1] Efforts to improve care for patients with SLE are needed. Digital quality measures leverage electronic health record (EHR), claims, registries, and other digital data by facilitating timely monitoring and improvement of healthcare quality on a population level.[2] Currently, several digital electronic clinical quality measures are tracked in the Rheumatology Informatics System for Effectiveness (RISE) Registry for rheumatoid arthritis and other conditions. Yet, to date, among measures by the National Quality Forum, Centers for Medicare and Medicaid Services, and 25 American College of Rheumatology (ACR) measures, not one is specific to SLE.[3]

As part of a collaboration between the Centers for Disease Control and Prevention and ACR, we sought to develop candidate quality measures for SLE based on available guidelines that could leverage longitudinal EHR data and the ACR RISE registry. Additionally, we aimed to evaluate importance and feasibility of potential measures, with the goal of prioritizing up to three measures for detailed testing. The ultimate goal is for eventual use of these SLE-specific digital quality measures in various national quality programs, including as part of the Centers' for Medicare and Medicaid Services (CMS) value-based care payment program known as the Quality Payment Program (QPP).

METHODS

We assembled an ACR workgroup of ten SLE experts (Supplemental Table 1), including practicing rheumatologists and researchers from diverse geographic and rural-urban settings across the United States and Canada. Members of the workgroup were selected based on a range of expertise in treating patients with SLE, health services research, research using longitudinal data from EHR, and quality measure development. Proposed quality measure statements, evidence summaries, and feasibility data developed by the workgroup were subsequently reviewed by a 17-member invited multidisciplinary Delphi panel, including rheumatologists, nephrologists, and a patient representative. With oversight from the workgroup, candidate measure development included five phases (Figure 1): 1) literature review with identification of evidence-based SLE quality constructs, 2) evaluation of the importance and feasibility of these constructs, 3) development of IF, THEN statements for SLE quality measures, 4) assessment of data availability in the RISE registry, and 5) modified Delphi exercise[5] with evaluation and prioritization of final proposed measure statements. *A priori*, we planned to advance up to three statements with high consensus for importance and feasibility, for further development, testing, and eventual implementation as digital quality measures.

Phase I: Literature Review and Identification of Evidence-Based SLE Quality Constructs

With assistance from a professional librarian, we conducted a literature search with PubMed, using MeSH terms for "systemic lupus erythematosus," "lupus," "lupus nephritis," and "practice guideline," and excluding terms "child," "infant," or "adolescent," to identify

all North American and European guidelines from 2000–2020 that focused on SLE or lupus nephritis (LN) management in adults; we similarly searched Ovid MEDLINE and Ovid Embase (Supplemental Figure 1). We reviewed all peer-reviewed, published studies in English with full text available. When the same society published updated guidelines within the date range, the most recent version was included.

ACR workgroup members reviewed guidelines meeting inclusion criteria to develop a list of all potential quality constructs across three domains agreed upon *a priori*: SLE treatment, monitoring, and phenotyping. The workgroup selected these domains as being highly specific to SLE; guideline recommendations in domains of preventive care (i.e., reproductive health, osteoporosis prevention) were excluded since these concepts were not SLE specific.

Phase II: SLE Quality Construct Importance and Feasibility Evaluation

The ACR workgroup rated the importance and feasibility of the preliminary constructs with an asynchronous web survey using a 9-point Likert scale.[5,6] Importance was specified as important for high quality SLE care on a population level. The highest score was 9, "extremely important," lowest score1, "not important." Feasibility specified whether an item would be feasible for implementation as a digital quality measure, utilizing EHR or other electronic health information. The highest score was 9 for "extremely feasible" with the lowest score of 1, "not feasible." Incorporating the RAND/UCLA Appropriateness Method,[7] consensus for high importance or high feasibility, respectively, was defined, *a priori*, as 60% of ratings 7 and 1 rating 3, after excluding one extreme low (i.e., 1–2) and one extreme high rating (i.e., 8–9).[5,6]

Phase III: SLE Quality Measure IF, THEN Statement Development

Informed by these ratings of the quality measure constructs, the workgroup then developed candidate IF, THEN statements for SLE quality measure constructs and accompanying evidence summaries. IF statements defined eligibility for the measures. All measures included adult populations age 18 years or over with SLE[8] or lupus nephritis, and clinical exclusions by measure were proposed.[9] THEN statements defined quality measure indicators as reflected in guideline literature.

Phase IV: Data Availability and Preliminary Gaps in Candidate SLE Quality Measures

Next, we queried data from the ACR's RISE registry to inform the feasibility of implementing the candidate SLE quality measures using data derived from the EHR, as well as to assess potential gaps in meeting these candidate measures to help inform the potential public health impact of implementation. RISE is a national registry that collects EHR data from rheumatology practices across the United States, including 1,000 US rheumatologists.[3] Available RISE data included diagnostic codes, medications, and laboratory data captured in structured EHR fields but did not include unstructured fields (i.e., narrative text, clinical notes, pathology reports, and other scanned documents).

We identified all participating RISE practices and patients who met published definitions of SLE or LN.[8,9] For each IF, THEN Statement, we assessed the proportion of RISE practices

with relevant data available and the preliminary proportion of patients who met the candidate measures in 2019. Failure to enter the numerator of a measure could reflect a lack of data availability or an actual gap in care. Findings were incorporated into a comprehensive Evidence Summary for the 15 candidate measures (Supplement 1 Appendix). This summary references relevant guideline recommendations, evidence, and RISE data availability that was shared with the panel in the project's next phase.

The Western Institutional Review Board determined that RISE is a quality improvement registry deemed minimal risk with a waiver of individual informed consent.

Phase V: Modified Delphi Process and Final Prioritization

The Delphi panel convened four virtual video conference meetings in November 2021, December 2021, January 2022, and February 2022 and completed two rounds of ratings for each IF, THEN quality measure statement. A final Delphi round was conducted to rank measures and arrive at a final group of three recommended measures. Before each meeting, the panel members were instructed to review several IF, THEN statements and the Evidence Summaries document and to complete the first round of rankings via an anonymous pre-meeting online survey. The panelists asynchronously ranked each IF, THEN statement for importance for high quality SLE care and feasibility for implementation as a digital quality measure. Importance was rated on a 4-point Likert scale (A-D), with the highest score A of "extremely important" and the lowest score D of "not important." Feasibility was rated on a 9-point Likert scale (9–1), with the highest score 9 of "extremely feasible" and the lowest score 1 of "definitely not feasible." *A priori*, consensus for importance was defined as 60% of ratings A-B and 1 rating of D, after excluding one extreme low (i.e., D) and one extreme high rating (i.e., A). Consensus for feasibility was defined as 60% of ratings 7 and 2 rating 3, after excluding one extreme low (i.e., 1–2) and one extreme high rating (i.e., 8–9).

During the Delphi meetings, we presented the results of the pre-meeting surveys. After discussing each measure, we conducted a real-time second round survey of anonymous ratings for each measure using the same scales for importance and feasibility. The IF, THEN quality measure statements that reached high consensus for importance and feasibility on the second round Delphi surveys were identified. The mean ratings for each statement were calculated and normalized on a 100-point scale, and statements were ranked from highest to lowest mean importance followed by highest to lowest mean feasibility.

In the final Delphi meeting, we presented round-2 survey results and discussed the IF, THEN quality measure statements that had achieved high consensus for importance and feasibility. The Delphi panel then completed a real-time, anonymous survey to rank the highest rated statements in order of perceived public health benefit. The panel aimed *a priori* to endorse two to three quality measures with the highest public health impact for further specification and testing as an SLE quality measure.

RESULTS

Literature Review and Evidence-Based SLE Quality Constructs

The literature review identified 85 relevant articles, and 10 met inclusion criteria.[10–19] The ACR workgroup distilled 57 quality measure constructs from these guidelines, including 15 in the treatment domain, 24 in the monitoring domain, and 18 in the phenotyping domain (Supplemental Table 2). Fifteen quality constructs reached high consensus for importance ratings and were advanced to generate SLE quality measures posed as IF, THEN statements (Table 1). We did not exclude constructs that did not meet consensus for feasibility at this stage.

SLE Quality Measure IF, THEN Statements

Treatment Domain—The treatment domain included seven quality measures. Nine guidelines supported the use of hydroxychloroquine by all people with SLE if there are no contraindications,[10,11,13–18,20] including the 2019 European League Against Rheumatism (EULAR) guidelines for SLE which gave an evidence Grade 1b/A.[10] Evidence supporting importance for SLE care included a systematic review including four small clinical trials and multiple observational studies indicating improvement in multiple outcomes, including lower flare rates, fewer renal relapses, reduced damage accumulation, improved overall survival, and possible prevention of thrombosis and atherosclerosis.[15,21–34] (Supplement 1 Appendix).

The second quality measure statement was to limit hydroxychloroquine dosing in patients with SLE to 5 mg/kg/day to minimize the risk of toxic retinopathy. This recommendation had an evidence Grade 3b/C, per 2019 EULAR guidelines, with evidence linking this dose-threshold to retinopathy risk based on observational data [25,35] but lacked evidence linking this dose threshold with efficacy for SLE treatment.

The third statement focused on limiting the prolonged use of glucocorticoids to doses to not exceed 7.5 mg/day for more than 6 months; this was recommended by seven guidelines[10,11,13,15–17,20] with evidence Grade 1b/B,[10] based on risks of long-term glucocorticoid toxicity and organ damage.[10,13,15,16,20,36–45] Six months was designated as the maximal duration for higher glucocorticoid dosing based on recommended induction regimens for LN and other organ-threatening disease.[11]

Next, four quality measures pertained to LN treatment, including the induction regimen for International Society of Nephrology/Renal Pathology Society (ISN/RPS) class III/IV LN, maintenance treatment for class III/IV LN, maintenance treatment for class V LN, and the use of angiotensin-converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs).[11,14,17,18,20] Induction treatment for class III/IV was recommended by nine guidelines,[10,11,13–18,20] with evidence from a systematic review of RCTs, and rated Grade 1a/A from 2019 Joint EULAR and European Renal Association-European Dialysis and Transplant Association (EULAR/ERA-EDTA) guidelines for LN,[11] Level A by 2012 ACR guidelines for LN,[14] and Grade 1b from 2012 consensus guidelines from the systemic autoimmune disease group (GEAS) of the Spanish Society of Internal Medicine (SEMI) and Spanish Society of Nephrology (SEN).[18] Voclosporin and belimumab are approved

as adjunctive but not stand-alone therapies for LN at the time of this review, and were not yet incorporated into published treatment guidelines, so they were not included in the quality measure statement. Class III/IV maintenance had a similar level of evidence. The IF, THEN statement on class V maintenance regimen was rated Grade 2b/B per 2019 EULAR/ ERA-EDTA guidelines for LN based on evidence from small clinical trials and cohort studies. The use of ACE/ARBs by patients with LN with over 0.5 grams/day proteinuria and with no contraindications (e.g., pregnancy or low blood pressure) was recommended by 6 guidelines and largely based on randomized controlled trial (RCT) data in patients with diabetic nephropathy; data were extrapolated for LN with one observational study in LN.[11,14,15,17,18,20]

Monitoring Domain—The monitoring domain included two quality measure statements for periodic laboratory monitoring, including SLE serologies and end-organ monitoring (i.e., nephritis, cytopenias), as well as one measure statement for disease activity monitoring using a validated instrument (e.g., SLE Disease Activity Index, British Isles Lupus Assessment Group). Multiple guidelines recommended periodic monitoring of anti-double stranded DNA (dsDNA) and complement c3 and c4 levels, although recommended frequencies varied or were not specified.[11,14–16,18–20] Monitoring for LN with urine protein, serum creatinine kidney function, or both, with or without complete blood count monitoring, was recommended by multiple guidelines with frequencies of at least every 6 months.[11,14–16,18–20] Recommendations to monitor urine protein and creatinine were Grade 1A and 2B, respectively, per 2019 EULAR/ERA-EDTA guidelines.[11] Kidney monitoring is requisite for prompt treatment to improve kidney outcomes and prognosis.[46,47] Routine monitoring of disease activity was EULAR recommended aiming at remission or low disease activity but they did not recommend specific validated instruments or frequency. Monitoring was recommended by Canadian and British Society of Rheumatology guidelines as Grade B with a low level of evidence for impacting SLE outcomes.[15,19]

SLE Phenotyping Domain—The SLE phenotyping domain included four IF, THEN statements. Three included laboratory assessment at the time of SLE diagnosis, including antiphospholipid antibody (aPL) testing, SLE-specific serologic testing (e.g., antinuclear antibodies (ANA), anti-dsDNA antibody, anti-Smith antibody, c3, and c4), and end-organ monitoring, including complete blood count to identify cytopenias and urinalysis and kidney function to assess for LN.[10,11,14–16,18,19] Testing for aPLs was recommended by multiple guidelines,[10,11,15,18,19] with grade 1A per the 2019 EULAR SLE treatment guidelines.[10] The fourth IF, THEN statement in the phenotype domain pertained to indications for kidney biopsy, including the identification of new, persistent proteinuria and/or unexplained worsening kidney function as recommended by multiple guidelines, with Grade B-C level evidence.[10,11,13–18,20] (Additional discussion in Appendix.)

Data Availability and Preliminary Identification of Measure Gaps in the RISE Registry

Across 226 practices representing >1,000 rheumatologists in the RISE registry,[3] we identified 35,859 patients with SLE and 4,826 patients with LN who had at least two rheumatology visits in 2019. Over 70% of patients were seen in single-specialty rheumatology practices; the mean number of annual visits was 4.2. Practice-level data

availability assessments showed that at least one source of medication records (e.g., medication reconciliation tables) was available for all RISE practices. Medication dose, required to assess candidate measures of safe dosing, was most often available via e-prescriptions or orders (versus medication reconciliation lists); e-prescriptions or orders were available for 73% of practices for hydroxychloroquine and 56% for glucocorticoids. Laboratory monitoring of dsDNA, complements, and urinalysis or quantitative urine protein were each available in more than 50% of practices. Only 6% of practices had structured data available containing kidney biopsy procedure codes or nephrology consults orders. LN class and dates of SLE/LN diagnosis were not reported in structured EHR fields.

Regarding preliminary measure-specific, patient-level data, 63% of patients with SLE had any documentation of hydroxychloroquine use in the assessment year.[48] Among hydroxychloroquine users with dosing information available, 67% received hydroxychloroquine at doses 5 mg/kg (Supplemental Appendix); hydroxychloroquine prescription dosing instructions or body weight values were missing for 29%. Few (0.3%) had a documented contraindication to hydroxychloroquine use according to International Classification of Diseases (ICD) codes for toxic retinopathy.

Glucocorticoids were used by 48% of patients with SLE in 2019. Over half (56%) of glucocorticoid users had prescription dosing instructions available, and 91% had pill size. The proportion using >7.5 mg/day for more than six months in 2019 was not readily available; as previously reported, 18.5% of glucocorticoid users with SLE in RISE used >7.5 mg/day for more than 90 days in 2018.[49]

As LN class was not available using structured data such as ICD codes, the proportions of patients with LN receiving recommended induction and maintenance therapy according to LN class are unknown. Just over one-third (36%) of patients with LN had documentation of ACE/ARB use. For end-organ monitoring, only 27% of patients with SLE and 32% with LN had 1 urinalysis or quantitative urine protein documented in 2019. For serologic monitoring, 51% with SLE had 1 dsDNA test and 37% had 1 c3 or c4 test documented in 2019. Regarding phenotype, ANA was available in structured EHR fields for 59% of SLE patients, likely because historic data or outside testing were not captured. The proportion with serologies at SLE diagnosis is likewise unknown. Fewer than 1% of patients had a SLE-specific disease activity score (e.g., SLEDAI) documented, although 39% with SLE had a Routine Assessment of Patient Index Data (RAPID-3) score reported on 1 occasion, which is not a lupus-specific measure.

This preliminary data assessment was presented to the Delphi panel to inform discussions regarding measure feasibility during the project's next phase.

Delphi Panel Discussion, Ratings, and SLE Quality Measure Endorsement

Of the 15 IF, THEN statements considered by the Delphi panel, five met high consensus for importance and feasibility: hydroxychloroquine use, limiting glucocorticoid doses exceeding 7.5 mg/day to ≤6 months, standardized screening for LN with end-organ monitoring for kidney function and urine protein excretion at least every 6 months, SLE serologies at

diagnosis (e.g., ANA, anti-dsDNA antibody, anti- Smith antibody, c3, and c4), and end-organ laboratory evaluation at diagnosis (Table 2).

In the treatment domain, hydroxychloroquine was noted to have benefits on multiple outcomes, including SLE disease activity, damage accumulation, and overall survival, and measuring prevalent hydroxychloroquine use would be feasible using EHR data. However, discussions regarding a hydroxychloroquine dosing quality measure included the paucity of data regarding the impact of dose thresholds on SLE outcomes as well as the emerging role of hydroxychloroquine blood levels in guiding dosing.

Glucocorticoid toxicity was noted as a major problem for patients with SLE and LN; reducing glucocorticoid exposure has potential to reduce long-term harm as well as improve outcomes. Discussion of this measure included the challenges of assessing glucocorticoid dose from EHR data, from pill size and number dispensed, since patients may be instructed on increases or tapers that are not documented on the prescription. Panelists discussed ongoing work in the RISE registry to make this possible. Discussion of measure thresholds for glucocorticoid dose and timing included evidence of harm over 7.5 mg daily and usual induction periods for severe manifestations of SLE, such as LN, of approximately 3–6 months.

In the lab monitoring domain, the panel noted there was strong consensus regarding the evidence to recommend creatinine kidney function and urinary protein monitoring due to the morbidity associated with LN and need for its prompt treatment. The panel concluded that either quantitative or qualitative urine protein measurement could fulfill this measure but preferred quantification. Overall, a quality measure to screen for or monitor LN among all patients with SLE was considered of broader public health impact than more frequent end-organ kidney monitoring limited only to patients with established LN.

In the disease phenotyping domain, discussion included the major challenge of identifying incident SLE and LN in EHR data as well as gaps in historic data. Baseline serologic testing and screening for LN or flare reached consensus for importance and feasibility but had lower average rankings than the three measures that achieved consensus (Table 2).

The Delphi panel discussions of remaining candidate SLE quality measures that did not reach consensus for importance and feasibility are reported in the Supplemental Appendix.

The final rankings for the top three recommended statements for patients with SLE were: 1) hydroxychloroquine use, 2) limiting glucocorticoids (to not exceed 7.5mg/d for more than six months), and 3) end-organ monitoring of kidney function and urine protein excretion at least every 6 months (Table 3).

Future Agenda

The Delphi panel endorsed a future infrastructure agenda to include building capacity to: 1) accurately capture SLE and LN diagnosis dates, 2) identify LN class such as with new ICD codes for specific International Society of Nephrology/Renal Pathology Society LN classification, and 3) improve interoperability to reliably retrieve laboratory and pathology results from outside the rheumatologist's EHR. These items were deemed important next

steps in the feasibility of additional future digital quality measures for SLE and LN. The Delphi panel additionally endorsed a research agenda to include: 1) Evidence for hydroxychloroquine dosing or blood levels and correlation with SLE outcomes and toxicity risks, 2) Evidence for SLE serologic/biomarker monitoring frequency and correlation with outcomes, and 3) Data on feasibility and impact of disease activity or damage monitoring in clinical practice. These items were deemed necessary to advance additional candidate SLE quality measures (Figure 2).

DISCUSSION

Using a literature review and modified Delphi process, we developed evidence-based quality measures for the longitudinal care of patients with SLE. These measures are recommended for future testing and potential implementation in EHRs, including the RISE registry. We reached consensus agreement and Delphi-panel endorsement of the top three quality measures for SLE, focused on hydroxychloroquine use, limiting the dose and duration of glucocorticoids, and regular kidney monitoring every 6 months to screen for and monitor lupus nephritis.

Despite documentation of gaps and disparities in SLE healthcare quality over the last decade, implementation of a national quality measure program to monitor and improve care has remained elusive.[1,50] Multiple factors have posed challenges, including the low prevalence of SLE disease, heterogeneity in disease manifestations and severity, a lack of consensus on outcome measures that are feasible to assess in clinical practice, and lack of a platform that facilitates quality measurement nationally.[1] Although our consensus panel agreed that many of these factors remain barriers, the robust platform of the RISE registry has increased the feasibility of advancing measures in several areas with potential for significant public health impact in the care of patients with SLE. Ensuring appropriate use of hydroxychloroquine in eligible patients, reducing glucocorticoid exposure and associated morbidity, and early detection of LN through appropriate screening and monitoring all have potential to reduce care gaps in SLE to ultimately improve patient outcomes. Moreover, our preliminary assessment of data in the RISE registry suggests that measurement is potentially feasible on a national scale.

Through this process, we also identified several important constructs for quality SLE care that were not deemed currently feasible for implementation as digital quality measures. Measures based on new onset SLE or LN were limited by data availability as the relevant dates of diagnosis and treatment initiation were not recorded in structured EHR fields. Information on LN class was additionally lacking, as were relevant dates of kidney biopsies. Therefore, while quality constructs related to LN induction treatment and maintenance treatment regimens according to LN class were rated highly important with relatively high-quality evidence, measures based on LN class were rated poorly for feasibility of implementation as digital quality measures. Therefore, this work informs a future agenda of infrastructure changes to EHR data availability and documentation (e.g., specific ICD codes for LN class or HCQ retinopathy) that would be needed to facilitate the implementation of digital quality measures pertaining to these important quality constructs.

We also identified areas where further evidence is needed, including hydroxychloroquine dosing or use of hydroxychloroquine blood levels to guide dosing, as well as the impact of serologic monitoring (e.g., dsDNA and complement tests) and the optimal frequency. Finally, we identified an evidence gap regarding the feasibility and impact of monitoring disease activity or damage in clinical practice. Although tracking outcomes should be a long-term goal of a national SLE quality measurement program, lack of consensus on a SLE disease activity measure that is feasible and useful to implement in clinical practice remains a barrier. A separate ACR workgroup is currently working on advancing a quality measure relating to patient-reported outcomes as a first step in tracking standardized outcomes in SLE.

Strengths of this work include the use of a rigorous literature review and modified Delphi process engaging a multidisciplinary panel of SLE experts representing various practice settings across the United States and Canada to develop a set of quality measures for SLE care that are candidates for further development as digital quality measures and national implementation. A limitation of this work is that while these recommended SLE quality measures are based on SLE guidelines, our literature review was limited to papers published in English and did not consider work published outside of North America and Europe, before 2000, or after June 2021. In addition, we acknowledge that development of quality measures is just the first step in developing digital quality measures and implementing these nationally. Prior to implementation, detailed measure specifications and testing will need to be undertaken. This will include assessment of measure feasibility (e.g., data availability, data accuracy, data standards, and workflows), measure reliability (e.g., quantification of the proportion of provider performance variation explained by true quality differences), measure validity (e.g., ensuring agreement between data elements and performance scores obtained by automated EHR abstraction and manual abstraction of the same information). Measures that are feasible, reliable, and valid will then be implemented in the RISE registry as part of a comprehensive quality improvement effort in SLE.

In conclusion, we present the first ACR quality measures for SLE, based on a rigorous, modified Delphi process involving an expert panel, informed by systematic literature review and initial feasibility testing. Prioritizing future public health impact, Delphi experts recommended three digital quality measures focused on hydroxychloroquine use, limiting glucocorticoid use, and kidney monitoring. Ultimately, these efforts aim to implement validated digital quality measures within US rheumatology practices to improve SLE outcomes.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgements:

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Significance and Innovations.

- Despite significant morbidity and mortality among patients with lupus, none of the 25 ACR quality measures specifically targets lupus.

- In collaboration with the ACR, multidisciplinary experts conducted a guideline review and modified Delphi process to generate and prioritize evidence-based quality measure statements for lupus.

- Emphasizing strong public health potential, panelists recommended three quality measures: 1) Hydroxychloroquine use, 2) Limiting glucocorticoid doses exceeding 7.5 mg daily to six months or less, 3) Measuring kidney function and urine protein at least as often as every six months.
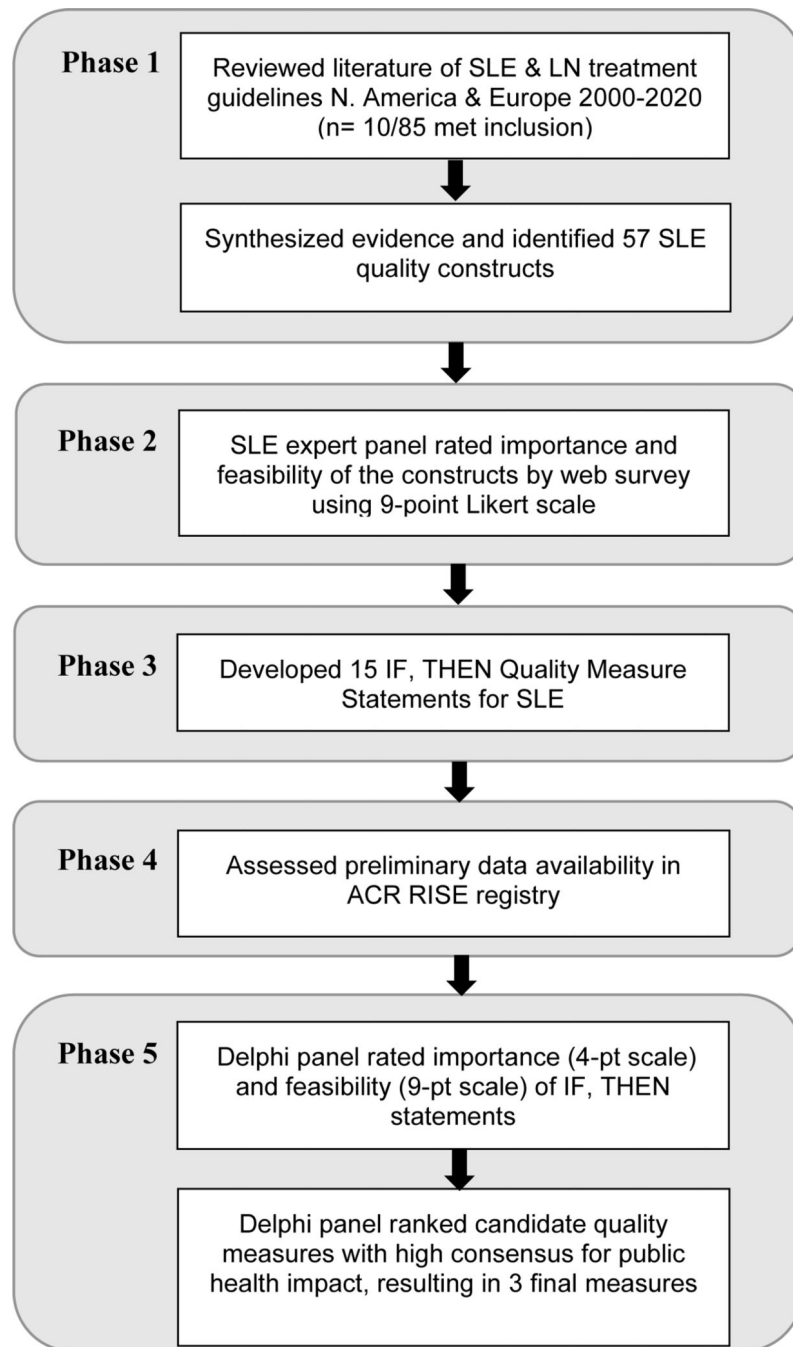
Figure 1.
Overview of the process to develop digital quality measures for SLE

RISE Data Infrastructure Agenda	
Goal	**Agenda Item**
SLE and LN diagnosis dates are retrievable from EHR data	Develop structured data fields across EHRs for SLE disease onset and LN diagnosis
LN class is retrievable from EHR data	Develop structured data fields across EHRs and new ICD codes for specific International Society of Nephrology/Renal Pathology Society LN classification
All laboratory tests are retrievable from EHR data, including tests performed outside the EHR	Incorporate outside laboratory tests into structured data fields across EHRs
Research Agenda	
Goal	**Agenda Item**
Consensus for the optimal hydroxychloroquine dosing strategy, balancing risks and benefits	Conduct research studies correlating hydroxychloroquine dose (or level) with SLE outcomes and risks
Optimal SLE serologic monitoring frequency is identified and linked with potential outcomes	Conduct research studies correlating SLE serologic monitoring frequency with outcomes
Evidence for feasibility and impact of disease activity or damage monitoring in clinical practice is established	Conduct research studies correlating disease activity or damage monitoring with outcomes and evaluating the feasibility of implementing these measures in clinical practice

Figure 2.
Future Agenda for Systemic Lupus Erythematosus Digital Quality Measures

Table 1.

Candidate Quality Measures for Adults with SLE

Domain	IF, THEN Quality Measure Statement
Treatment	**HCQ Use**
IF	a patient has SLE,
THEN	they should have a prescription for hydroxychloroquine in the measurement year unless a contraindication or adverse event is documented in the medical record.
Treatment	**HCQ Dose**
IF	a patient with SLE is receiving hydroxychloroquine,
THEN	the most recent dose prescribed should be 5 mg/kg/day.
Treatment	**Limit Glucocorticoid Use**
IF	a patient has SLE,
THEN	the glucocorticoid dose should not exceed 7.5 mg/day of prednisone (or equivalent) for more than 6 months.
Treatment	**Lupus Nephritis Class III/IV Induction**
IF	a patient with SLE has new Class III or IV nephritis and is not pregnant,
THEN	induction therapy with mycophenolate or intravenous cyclophosphamide should be administered within 3 months of kidney biopsy or diagnosis.
Treatment	**Lupus Nephritis Class III/IV Maintenance**
IF	a patient with SLE has been diagnosed with Class III or IV nephritis and is not pregnant,
THEN	they should be placed on therapy for at least 2 years with mycophenolate, azathioprine, or a calcineurin inhibitor.
Treatment	**Lupus Nephritis Class V Maintenance**
IF	a patient with SLE has been diagnosed with Class V nephritis,
THEN	they should be placed on therapy for at least 2 years with either mycophenolate, a calcineurin inhibitor, or azathioprine.
Treatment	**ACE/ARB Use in Lupus Nephritis**
IF	a patient with lupus nephritis has proteinuria of >0.5g/24 hours on two occasions,
THEN	they should be treated with an ACE inhibitor or angiotensin receptor blocker in the absence of contraindications.
Monitoring	**End-Organ Lab Monitoring in SLE**
IF	a patient has SLE,
THEN	measurement of both kidney function and protein excretion (urinalysis and/or quantitative measurement) should be performed at least every 6 months.
Monitoring	**End-Organ Lab Monitoring in Lupus Nephritis**
IF	a patient has a history of lupus nephritis,
THEN	CBC, urinalysis, and quantitative measurement of kidney function and protein excretion should be performed every 3 months.
Monitoring	**SLE Disease Activity or Damage**
IF	a patient has SLE,
THEN	disease activity should be measured using a validated instrument at more than half of visits in the measurement year.
Monitoring	**SLE Periodic Serologies**
IF	a patient has SLE,
THEN	the serum complements c3/c4 and anti-dsDNA antibody levels should be checked at least every 6 months.
Phenotype	**End-Organ Labs at SLE Diagnosis**
IF	a patient has SLE,

Domain	IF, THEN Quality Measure Statement
THEN	CBC, creatinine, urinalysis, and a measure of urine protein should be performed within 6 months of diagnosis.
Phenotype	**SLE Diagnosis Serologies**
IF	a patient has SLE,
THEN	ANA, anti-dsDNA antibody, anti-Smith antibody, c3, and c4 should be performed within 6 months of diagnosis.
Phenotype	**Kidney Biopsy Indications**
IF	a patient with SLE has new persistent (e.g., 500mg of proteinuria in 24 hours on two occasions), and/or worsening of serum creatinine (>30% elevation from baseline) and has not had prior LN diagnosis or biopsy within 1 year,
THEN	a referral for a kidney biopsy should be placed.
Phenotype	**Antiphospholipid Antibody Laboratory Testing at SLE Diagnosis**
IF	a patient has SLE,
THEN	antiphospholipid antibodies (anticardiolipin IgG and IgM, beta 2 glycoprotein IgG and IgM, and lupus anticoagulant) should be checked within 1 year of SLE diagnosis.

ACE, angiotensin converting enzyme inhibitor; ANA, antinuclear antibody; ARB, angiotensin receptor blocker; CBC, complete blood count; dsDNA, double stranded DNA; HCQ, hydroxychloroquine; LN, lupus nephritis; SLE, systemic lupus erythematosus

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Table 2.

Delphi Consensus* Results for Quality Measure Statements

IF, THEN Statements	Consensus for High Importance	Mean Importance	Consensus for High Feasibility	Mean Feasibility
1. Treatment: HCQ use	**yes**	**97.9**	**yes**	**83.3**
2. Treatment: HCQ dose	no	61.7	no	63.7
3. Treatment: Limit GC use	**yes**	**87.5**	**yes**	**77.8**
4. Treatment: LN induction	yes	100.0	no	59.0
5. Treatment: LN class III/IV maintenance	yes	92.7	no	60.8
6. Treatment: LN class V maintenance	no	68.8	no	53.7
7. Treatment: ACE/ARB use in LN	no	69.6	no	64.1
8. Monitoring: SLE end-organ labs	**yes**	**92.9**	**yes**	**84.6**
9. Monitoring: LN end-organ labs	yes	89.3	no	65.9
10. Monitoring: SLE disease activity or damage	no	61.7	no	42.2
11. Monitoring: SLE serologies	no	48.2	yes	82.5
12. Phenotype: End-organ tests at SLE diagnosis	**yes**	**75.0**	**yes**	**85.5**
13. Phenotype: SLE diagnosis serologies	**yes**	**73.1**	**yes**	**78.7**
14. Phenotype: Kidney biopsy indications	yes	85.7	no	55.6
15. Phenotype: aPL testing at SLE diagnosis	yes	75.0	no	72.2

*
 n=12–17 voters per measure; Importance was assessed on a 4-category ordinal scale (A=4=extremely important; D=1=not important); feasibility on a 9-point scale (1=definitely not feasible; 9=extremely feasible); both were normalized to a 100-point scale.

Abbreviations: ACE=angiotensin converting enzyme inhibitor, aPL= antiphospholipid antibody, ARB=angiotensin receptor blockade, GC=glucocorticoid, HCQ=hydroxychloroquine, LN=lupus nephritis, SLE=systemic lupus erythematosus.

Table 3.

Final Rank of Quality Measure Statements with High Consensus by Public Health Benefit for Quality SLE Care

Final Rank	IF, THEN Statement	Ranked 1st	Recommend inclusion[*]
1st	IF a patient has SLE, THEN they should have a prescription for hydroxychloroquine on or after the date of the most recent rheumatology visit unless a contraindication or adverse event is documented in the medical record.	55.6%	100%
Public Health Impact: Lower SLE flare rate; fewer kidney relapses; reduced damage accumulation; pregnancy safety and benefits; improved survival in observational studies; possible prevention of thrombosis and cardiovascular disease.[15,21–34]			
2nd	IF a patient has SLE, THEN the glucocorticoid dose should not exceed 7.5 mg/day prednisone (or equivalent) for more than 6 months.	33.3%	100%
Public Health Impact: Long-term glucocorticoid therapy can cause irreversible organ damage, and doses 7.5 mg/day indicate patient does not meet Lupus Low Disease Activity State. Prednisone dose <7.5 mg/day is associated with lower risk of cataracts, osteoporotic fractures, and cardiovascular disease vs. higher dose.[10,13,15,16,20,36–45]			
3rd	IF a patient has SLE, THEN measurement of both kidney function and protein excretion (urinalysis and/or quantitative measurement) should be performed at least every 6 months.	11.1%	100%
Public Health Impact: Spot UPCr correlates with 24-hour protein in most studies in detecting nephritis; proteinuria can indicate lupus nephritis flare and can be used to monitor treatment response; proteinuria and creatinine at 6–12 months predict LN prognosis; low proteinuria at 1 year predicts better long-term kidney outcomes.[46,47]			

[*] Items recommended to be included for SLE quality measure specification and testing in the RISE registry (n=9 voters). Abbreviations: SLE=systemic lupus erythematosus; UPCr=urine protein to creatinine ratio; LN=lupus nephritis.