

## APPENDIX

### A systematic review of Patient-Reported Outcome (PRO) Measures for Use in Randomized Controlled Trials (RCT) of Patients with Systemic Lupus Erythematosus (SLE)

Search Methods  
October 20, 2019

1. Search methods will include multiple methods to ensure a sensitive search of literature across geographical and discipline areas and to ensure that all applicable literature is found. These search methods include searching multiple databases, and citation searching of reference lists of included studies.

#### 1.1. Two Databases

The goal of the initial database searches is to capture the breadth of multidisciplinary literature. The databases to be included in this review are:

- Ovid Medline: the United States National Library of Medicine's (NLM) premier bibliographic database providing information from the following fields: medicine, nursing, dentistry, veterinary medicine, allied health and pre-clinical sciences
- Embase: a biomedical and pharmacological database containing bibliographic records with citations, abstracts and indexing derived from biomedical articles in peer reviewed journals, and is especially strong in its coverage of drug and pharmaceutical research. Better captures European literature.

#### 1.2 Search Terms

- Search terms:
  - **Appendix I** for Medline

— **Appendix II** for Embase

### 1.3 Search Parameters/Limiters

- Limiters will be added once all search terms (OR/AND) combined.
  - Articles written in English language (secondary to the language limitations of reviewers) and human studies only (secondary to the objective of the review)
- Searches will not be limited by age group or year (year up to date of search)
  - Searches will not be limited by “review;” reviews will be filtered out during screening/selection process. Related reviews will be noted and references will be checked for applicable included articles

### 1.4 Running database searches

- The literature searches will be completed by librarian/information specialist (EVIDERA Team), who has extensive experience in database searching and systematic reviews.
- The primary search will be done for Medline database and then altered as necessary for other databases.
- Searches will be tailored to each database based on the above terms.
- Copies of each search structure per database will be retained.
- The librarian will remove duplicates within and between databases
- Key articles (**Appendix III**) will be provided to validate the search developed by the librarian and to supplement the library with important literature

### 1.5 Citation search

- Using screening/selection process (**Appendix IV**)
- Title search will be completed by primary reviewer (Member of EVIDERA)
- Both reviewers will use independent-agreement process to screen/select abstracts and then full articles.

### 1.6 Hand Search reference lists of relevant recent reviews

- Described in **Appendix I-II**
- Using screening/selection process (**Appendix IV**)
- Title/abstract/full-article screening will be completed by primary reviewer (LE) to make list of any new included articles
- 2<sup>nd</sup> reviewer will check to see if any new included articles meet inclusion criteria

### Appendix 1: Search terms for Medline

Friday, June 23, 2017 5:45:31 PM Database - MEDLINE Complete		
#	Query	Results
S1	AB "systemic lupus erythematosus" OR MM "Lupus Erythematosus, Systemic" OR TI "systemic lupus erythematosus"	54,488
S2	PT "randomized controlled trial" OR "Randomized Controlled Trials as Topic" OR AB (rct OR random*) OR TI (rct OR random*)	1,075,153
S3	AB (SF-36 OR SF36 OR "Short Form 36" OR "36 SF") OR TI (SF-36 OR SF36 OR "Short Form 36" OR "36 SF")	21,385
S4	AB (Lupus-QOL OR "Lupus Quality of Life" OR LupusQOL) OR TI (Lupus-QOL OR "Lupus Quality of Life" OR LupusQOL)	38
S5	AB (FACIT-F OR ("Functional Assessment of Chronic Illness Therapy" AND Fatigue)) OR TI (FACIT-F OR ("Functional Assessment of Chronic Illness Therapy" AND Fatigue))	311
S6	(S1 AND S2) AND (S3 OR S4 OR S5)	35
S7	S6 AND DT 2015-2017 AND LA english AND PT "journal article"	8
S8	PT "observational study" OR MH "Observational Studies as Topic" OR AB observational OR TI observational	135,514
S9	(S1 AND S8) AND (S3 OR S4 OR S5)	10

<b>S10</b>	S9 AND DT 2015-2017 AND LA english AND PT "journal article"	4
<b>S11</b>	AB (validity OR validation OR development OR psychometric) OR TI (validity OR validation OR development OR psychometric) OR MH psychometrics	1,994,875
<b>S12</b>	TI (SF-36 OR SF36 OR "Short Form 36" OR "36 SF")	1,116
<b>S13</b>	(S12 OR S4 OR S5) AND S11 AND LA english	511

### Appendix II: Search terms for Embase

Embase Session Results (23 Jun 2017)		
No.	Query	Results
#1	'systemic lupus erythematosus'/exp/mj AND 'systemic lupus erythematosus':ab,ti	37436
#2	randomized controlled trial'/exp OR 'randomized controlled trial (topic)'/exp OR rct:ab,ti OR random*:ab,ti	1354497
#3	'sf-36':ab,ti OR 'sf36':ab,ti OR 'short form 36':ab,ti OR '36 sf':ab,ti OR 'short form 36'/exp	40482
#4	'lupus-qol':ab,ti OR 'lupus quality of life':ab,ti OR lupusqol:ab,ti	95
#5	'facit-f':ab,ti OR ('functional assessment of chronic illness therapy':ab,ti AND 'fatigue':ab,ti)	735
#6	#1 AND #2 AND (#3 OR #4 OR #5)	65
#7	#6 AND ([article]/lim OR [article in press]/lim) AND [2015-2017]/py AND [english]/lim	9
#8	'observational study'/exp OR observational:ab,ti	206795
#9	#1 AND #8 AND (#3 OR #4 OR #5)	18
#10	#9 AND ([article]/lim OR [article in press]/lim) AND [2015-2017]/py AND [english]/lim	2

#11	'validity'/exp/mj OR validation:ab,ti OR validity:ab,ti OR development:ti OR psychometric:ab,ti	778101
#12	'sf-36':ti OR 'sf36':ti OR 'short form 36':ti OR '36 sf':ti OR 'short form 36'/mj	2066
#13	#12 OR #4 OR #5 AND #11 AND [english]/lim	557

### Appendix III: Key articles used to validate the search and to supplement the library important literature

Key Articles used to initially validate key search terms at title, keyword and abstract levels. These articles should be captured in data-base search. See reference list for full citation.

- Strand V, Russell AS. Workshop report: WHO/ILAR Taskforce on Quality of Life. *J Rheumatol* 1997; 24:1630-3.
- Jolly M. How does quality of life of patients with systemic lupus erythematosus compare with that of other common chronic illnesses? *J Rheumatol* 2005; 32:1706-8.
- Gladman D, Urowitz MB, Ong A, Gough J, MacKinnon A. Lack of correlation among the 3 outcomes describing SLE: disease activity, damage and quality of life. *Clin Exp Rheumatol* 1996; 14:305-8.
- Strand V, Gladman D, Isenberg D, Petri M, Smolen J, Tugwell P. Outcome measures to be used in clinical trials in systemic lupus erythematosus. *J Rheumatol* 1999; 26:490-7.
- McElhone K, Abbott J, Teh L-S: A review of health related quality of life in systemic lupus erythematosus. *Lupus* 2006; 15:633-43.
- Dua AB, Touma Z, Toloza S, Jolly M: Top 10 recent developments in HRQOL in patients with systemic lupus erythematosus. *Curr Rheumatol Rep* 2013; 15:380
- Bruce IN, Mak VC, Hallett DC et al: Factors associated with fatigue in patients with systemic lupus erythematosus. *Ann Rheum Dis* 1999; 58:379-81.

- Petri M, Kawata AK, Fernandes AW, et al. Impaired health status and the effect of pain and fatigue on functioning in clinical trial patients with systemic lupus erythematosus. *J Rheumatol*. 2013; 40:1865-1874.
- Schmeding A, Schneider M. Fatigue, health-related quality of life and other patient-reported outcomes in systemic lupus erythematosus. *Best Pract Res Clin Rheumatol*. 2013; 27:363-375.
- Sterling K, Gallop K, Swinburn P, et al. Patient-reported fatigue and its impact on patients with systemic lupus erythematosus. *Lupus*. 2014; 23:124-132
- Ad Hoc Committee on Systemic Lupus Erythematosus Response Criteria for Fatigue. Measurement of fatigue in systemic lupus erythematosus: a systematic review. *Arthritis Rheum*. 2007; 57:1348-57.
- Strand V, Galateanu C, Phushparajah D, Nikai E, Sayers J, Wood R, van Vollenhoven RF: Limitations of current treatments for systemic lupus erythematosus: a patient and physician survey. *Lupus* 2013; 22: 819-26.
- Gordon C, Isenberg D, Lerstrøm K, et al. The substantial burden of systemic lupus erythematosus on the productivity and careers of patients: a European patient-driven online survey. *Rheumatology (Oxford)*. 2013; 52:2292-2301.
- Strand V, Gladman D, Isenberg D, Petri M, Smolen JS, Tugwell P. Endpoints: consensus recommendations from OMERACT IV. *Outcome Measures in Rheumatology*. *Lupus* 2000; 9:322-7.
- Stoll T, Gordon C, Seifert B, Richardson K, Malik J, Bacon PA, et al. Consistency and validity of patient administered assessment of quality of life by the MOS SF-36; its association with disease activity and damage in patients with systemic lupus erythematosus. *J Rheumatol* 1997; 24:1608-14.
- Mahieu M, Yount S, Ramsey-Goldman R: Patient reported outcomes in Systemic Lupus Erythematosus. *Rheum Dis N Am* 2016; 42:253-63.
- Castelino M, Abbott J, McElhone K, Teh L-S: Comparison of the psychometric properties of health related quality of life measures used in adults with systemic lupus erythematosus: a review of the literature. *Rheumatology* 2013; 52:684-696.
- McElhone K, Abbott J, Shelmerdine J, Bruce IN, Ahmad Y, Gordon C, et al. Development and validation of a disease-specific health-related quality of life

- measure, the LupusQoL, for adults with systemic lupus erythematosus. *Arthritis Rheum* 2007; 57:972-9.
- McElhone K, Abbott J, Gray J et al. Patient perspective of systemic lupus erythematosus in relation to health-related quality of life concepts: a qualitative study. *Lupus* 2010; 19:1640-7.( McElhone K, Abbot J, Williams A, et al. Patient perspective of systemic lupus erythematosus in relation to health-related quality of life concepts: a qualitative study. *Lupus*. 2010;19:1640-1647.)
  - Jolly M, Pickard SA, Mikolaitis RA et al. LupusQoL-US Benchmarks for US Patients with Systemic Lupus Erythematosus. *J Rheumatol* 2010; 37:1828–33
  - García-Carrasco M, Mendoza-Pinto C, Cardiel MH, et al. Health related quality of life in Mexican women with systemic lupus erythematosus: a descriptive study using SF-36 and LupusQoL. *Lupus*. 2012; 21:1219-1224.
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  - Hosseini N, Bonakdar ZS, Gholamrezaei A, et al. Linguistic validation of the LupusQoL for the assessment of quality of life in Iranian patients with systemic lupus erythematosus. *Int J Rheumatol* 2014:1515-30.
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- Clowse MEB, Wallace DJ, Furie RA et al: Efficacy and Safety of Epratuzumab in Moderately to Severely Active Systemic Lupus Erythematosus Results From Two Phase III Randomized, Double-Blind, Placebo-Controlled Trials *Arth Rheum* 2017; 69:362-75.
- Devilliers H, Amoura Z, Vesancenot J-F et al. Responsiveness of the 36-item Short Form Health Survey and the Lupus Quality of Life questionnaire in SLE. *Rheumatology* 2015; 54:940-49 [repeat]
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#### Appendix IV: Criteria for screening and selection process

	Include	Exclude
<i>Title and abstract level</i>	<ul style="list-style-type: none"> <li>• <b>Population: Should</b> include Individuals experiencing SLE</li> <li>• <b>Outcome: Should</b> include description of concept related to health-related quality of life – SF-36, LupusQoL or FACIT-F</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Population:</b> Not SLE</li> <li>• <b>Outcome:</b> Not focused on health-related quality of life – SF-36, LupusQoL or FACIT-F</li> </ul>
<i>Full Article Level</i>	<ul style="list-style-type: none"> <li>• <b>Population:</b> Adult SLE diagnosis for the participants. If mixed diagnostic population, results will be excluded</li> <li>• <b>Outcome:</b> quality of life – particularly on SF-36, LupusQoL or FACIT-F</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Any exclusion from title level</b></li> <li>• <b>Hierarchy of exclusion:</b> <ol style="list-style-type: none"> <li>1. Article not in English</li> <li>2. Full-text not available (i.e. abstract for conference) or not able to find full-text using multiple sources.</li> <li>3. Not peer-reviewed published evidence (e.g., grey literature, magazine article, thesis dissertation)</li> <li>4. Secondary report of the literature (review, book chapter, opinion report/editorial)</li> <li>5. Does not have quantitative data.</li> <li>6. <b>Population:</b> Does not include adult SLE diagnosis for participants.</li> <li>7. <b>Population:</b> If mixed population.</li> </ol> </li> <li>• <b>Outcome:</b> Does not report quality of life – particularly on SF-36, LupusQoL or FACIT-F</li> </ul>

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