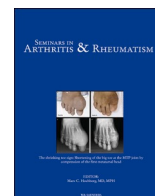




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OMERACT 2023 Systemic Lupus Erythematosus Special Interest Group: Winnowing and Binning Preliminary Candidate Domains for the Core Outcome Set

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ABSTRACT

Background: The Outcome Measures in Rheumatology (OMERACT) Systemic Lupus Erythematosus (SLE) Working Group held a Special Interest Group (SIG) at the OMERACT 2023 conference in Colorado Springs where SLE collaborators reviewed domain sub-themes generated through qualitative research and literature review.

Objective: The objective of the SIG and the subsequent meetings of the SLE Working Group was to begin the winnowing and binning of candidate domain sub-themes into a preliminary list of candidate domains that will proceed to the consensus Delphi exercise for the SLE COS.

Methods: Four breakout groups at the SLE SIG in Colorado Springs winnowed and binned 132 domain sub-themes into candidate domains, which was continued with a series of virtual meetings by an advisory group of SLE patient research partners (PRPs), members of the OMERACT SLE Working Group Steering Committee, and other collaborators.

Results: The 132 domain sub-themes were reduced to a preliminary list of 20 candidate domains based on their clinical and research relevance for clinical trials and research studies.

Conclusion: A meaningful and substantial winnowing and binning of candidate domains for the SLE COS was achieved resulting in a preliminary list of 20 candidate domains.

Background

Outcome Measures in Rheumatology (OMERACT) was established and held its first conference in 1992¹. OMERACT has pioneered the development of Core Outcome Sets (COS) guiding and standardizing outcome measures and the reporting of outcomes in randomized controlled trials (RCTs) and longitudinal observational studies (LOSs) of different rheumatic diseases¹⁻⁵. The first OMERACT Systemic Lupus Erythematosus (SLE) Working Group developed the initial OMERACT SLE COS in 1998^{6,7}. However, the 1998 OMERACT SLE COS never proceeded to measurement instrument selection⁸ and lacked patient participation and representation.

Since 1998, several novel SLE domains have been identified and new measures for assessing treatment outcomes have been developed, generating a need to establish a new OMERACT SLE COS⁹. For this purpose, we initiated the OMERACT SLE Working Group in 2018 which currently has 220 members representing over 25 countries and 5 continents.

The new OMERACT SLE Working Group has undertaken 3 endeavors to generate a list of candidate domains to consider for the OMERACT SLE COS. Although still ongoing, these projects have already yielded preliminary results of candidate domain sub-themes. The first of the projects is a survey of SLE domains administered to the OMERACT SLE Working Group and 100 patients from the University of Toronto Lupus Program at the University Health Network. The survey asked responders to rate known SLE domains on their importance for the SLE COS and suggest additional candidate domains to consider. The second project is a scoping literature review of SLE clinical trials and systematic reviews since 2010. Screening yielded 600 articles which are currently in the data extraction phase. The final project is 6 separate focus groups held with 36 patients with SLE (3-10 patients per meeting) representing 5 continents. Transcripts of the focus groups are being thematically analyzed for candidate domains. All 3 projects are expected to be completed in the coming months and published. The preliminary results of the domain generation projects yielded a total of 132 domain sub-themes.

OMERACT holds conferences every 2 years for rheumatic diseases and measurement working groups to come together in order to advance the disease specific and non-specific development and methods of establishing Core Outcome Sets (COS). During the OMERACT 2023 Conference held in Colorado Springs, CO, USA, the OMERACT SLE Working Group conducted a Special Interest Group (SIG). The objective

of the SIG and the subsequent meetings of the SLE Working Group was to begin the winnowing and binning of candidate domain sub-themes into a preliminary list of candidate domains that will proceed to the consensus Delphi exercise for the SLE COS.

Methods

SLE Special Interest Group

Attendees of the SLE SIG were split into 3 breakout groups of in-person attendees and 1 of virtual-attendees each consisting of 10-12 participants. The OMERACT SLE Working Group was able to fund 1 patient research partner (PRP) (MD), diagnosed with SLE, to attend the OMERACT conference. The first in-person breakout group had our SLE PRP, and the second and third breakout group had 2 PRPs from other rheumatic conditions attending the conference participate. The online breakout group had another PRP diagnosed with SLE participate. Each breakout group had 1 facilitator to guide discussion and 1 scientific reporter to record discussion points and domain sub-theme grouping decisions. Each group was given a unique list of 33-34 domain sub-themes due to the high volume generated from the above listed projects (contextual factors were already removed by the Steering Committee). Each breakout group reviewed its list of domain sub-themes one at a time, deciding for each domain sub-theme whether it was a domain on its own, too large a topic needing to be divided into separate domains, or too specific and needing to be absorbed into another domain. Domain sub-themes were considered based on their clinical and research relevance keeping in mind research and cohort studies. Final candidate domains would be feasible and meaningful outcomes to capture in clinical trials and research studies. The scientific reporter brought the discussion report to the fellow (WN) who compiled results from the breakout groups.

Advisory Group

After the OMERACT conference, an advisory group for the OMERACT SLE Working Group was established consisting of 3 rheumatologists from the Steering Committee (VS, LS, ZT), 2 rheumatologist who attended the OMERACT SLE SIG Session and available to meet weekly and desired to be involved in the advisory group (IP, AK), 2 PRPs (MD, YE) diagnosed with SLE, and 1 fellow (WN). Members were selected on attendance of the OMERACT SLE SIG Session, desire to participate in future work, and their ability to meet the time commitment required for

the advisory group to meet regularly. The advisory group met once per week for 1.5 hours for a total of 7 meetings following the OMERACT conference. Firstly, the advisory group reviewed the compiled results of the breakout groups and their winnowing and binning of preliminary domain sub-themes to a list of preliminary candidate domains. The advisory group continued to meet to further winnow and bin the list of preliminary candidate domains down to a more concise list of candidate domains.

RESULTS

The 132 preliminary domain sub-themes generated from the 3 domain generation projects (left column of Table 1) were winnowed and binned by the breakout groups. The results of the breakout groups was further reviewed, winnowed, and binned by the advisory group into the 20 candidate domains (right column of Table 1).

Conclusion

We have achieved a substantial and meaningful reduction of candidate domains. Preliminary results of the domain generation projects generated 132 preliminary domain sub-themes. The breakout groups held at the SLE SIG at the OMERACT Conference and our advisory group winnowed and binned these domain sub-themes down to 20 candidate domains, and ideal and manageable number of domains for the next stage in SLE COS development.

The 5 domains from the 1998 SLE COS (Adverse Events, Economic Cost Impact, Health Related Quality of Life, Organ Damage, and SLE Disease Activity) carried over to our candidate domain list. There were 3 other domains from the 1998 SLE COS research agenda that have made our list of candidate domains (Fatigue, Patient Global Assessment of Disease Activity, Physician Global Assessment of Disease Activity), as well as 3 candidate domains that were alluded to from 1998 SLE COS research agenda domains (Physical Function, Emotional Health, Participation). The other 9 candidate domains in our list are new distinct domains (Cognition, Flares, Frailty, Pain Interference, Pain Intensity, Sexuality, Sleep Disturbance, Treatment Satisfaction, Use of Corticosteroids Including Tapering).

Future Steps

The 3 domain generation projects being conducted by the OMERACT SLE Working Group are nearing completion. We are currently in the process of further analysing the results of the scoping review and focus groups, and we aim to complement and further update the list of domains reported in Table 1. Definitions for each of the candidate domains will also be agreed upon with a definition survey administered to SLE collaborators including SLE patients before moving forward with the Delphi. These candidate domains will be put through a 4 round Delphi consensus exercise to determine the importance of domains to SLE collaborators, selecting the most important domains for the SLE COS. The Delphi will yield a Core Domain Set (CDS), for which each core domain will proceed through measurement instrument selection ensuring that the selected instruments demonstrate appropriate measurement properties. The combined CDS with their measurement instruments will form the updated OMERACT SLE COS.

Declaration of competing interest

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Table 1

Preliminary list of candidate SLE domains and sub-themes sorted alphabetically

Preliminary Domain Sub-themes (n=132)	Candidate Domains (n=20)
1. Adverse events	1. Adverse Events (including death)
2. Burden from medication	
3. Burden of treatment	
4. Drug interactions	
5. Fertility	
6. Mortality	
7. Nausea	
8. Steroid side effects	
9. Tolerability	
10. Treatment side effects	
11. Attention	2. Cognition
12. Brain fog	
13. Cognition/cognitive function	
14. Cognitive coping strategies	
15. Cognitive flexibility	
16. Cognitive impairment	
17. Communication cognitive challenges	
18. Coping mechanisms	
19. Episodic memory	
20. Inhibitory control	
21. Memory	3. Economic Cost Impact
22. Processing speed	
23. Prospective memory	
24. Working memory	
25. Cost (medication, non-medical like lotion, alternative medicine, affordability)	
26. Economic Cost	
27. Financial strain of illness	
28. Time off work, impact on employment	
29. Appearance	
30. Anger	
31. Anxiety	
32. Anxiety about coping with disease uncertainty	
33. Body image	
34. Changes in personality	
35. Depressed about no longer being the same	
36. Depressed feelings	
37. Depression	
38. Depression about coping with disease uncertainty	
39. Embarrassed	
40. Fear	5. Fatigue
41. Frustration	
42. Future perspective, hope, optimism	
43. Guilt	
44. Identity	
45. Intimacy	
46. Irritability	
47. Isolation	
48. Lack of healthcare awareness of SLE	
49. Lack of understanding by others/ misunderstood invisible disease	
50. Learned helplessness	
51. Loneliness	
52. Loss of confidence	
53. Mental health	
54. Mood changes	
55. Mood swings	
56. Postponing parenthood	
57. Psychosocial health/factors	
58. Resilience	
59. Sadness	
60. Self-concept	
61. Self-efficacy	
62. Self-esteem	
63. Social isolation and exclusion	
64. Time consumption by disease	
65. Time taken by appointments	
66. Worry	
67. Emotional fatigue	
68. Fatigue	
69. Lack of energy	

(continued on next page)

Table 1 (continued)

70. Physical fatigue	
71. Tiredness	
72. Flares	6. Flares
73. Frailty	7. Frailty
74. Burden to others/impact on others	8. Health Related Quality of Life
75. Health related quality of life	
76. Quality of life	
77. Stress	
78. Damage	9. Organ Damage
79. Pain intensity	10. Pain Intensity
80. Pain interference	11. Pain Interference
81. Employment/work status	12. Participation (<i>In family, social, education, work, and leisure activities</i>)
82. Impaired parenting	
83. Relationship impact	
84. Role participation	
85. Social functioning Relationship impact	
86. Patient global assessment of disease activity	13. Patient Global Assessment of Disease Activity
87. Coping mechanisms	14. Physical Function
88. Disability	
89. Gradual disability	
90. Impairment	
91. Lifestyle restrictions	
92. Loss of physical ability	
93. Mobility	
94. Physical activity	
95. Physical fitness	
96. Physical functioning/functional ability	
97. Physically unreliable body	
98. Reduced activity	
99. Weakness	
100. Physician global assessment of disease activity	15. Physician Global Assessment of Disease Activity
101. Sexual dissatisfaction	16. Sexuality
102. Sexuality	
103. Sexuality and drive reduced	
104. Aching	17. SLE Disease Activity
105. Arthritis	
106. Disease activity	
107. Disease activity state/status/remission	
108. Disease severity	
109. Dizziness	
110. Eye pain, itching, red	
111. Fever	
112. Hair Loss	
113. Headache	
114. Kidney specific problems	
115. Muscle spasms	
116. Muscle weakness	
117. Musculoskeletal	
118. Numbness	
119. Physical changes (weight gain)	
120. Raynaud's phenomenon	
121. Resilience	
122. Self-management	
123. Skin manifestations	
124. Soreness	
125. Stiffness	
126. Swollen body	
127. Swollen joints	
128. Vision impairment/eye problems	
129. Weakness	
130. Sleep	18. Sleep Disturbance
131. Satisfaction	19. Treatment Satisfaction
132. Use of corticosteroids including demonstrated tapering	20. Use of Corticosteroids Including Tapering

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