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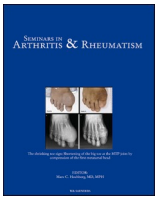

The Sjögren's Working Group: The 2023 OMERACT meeting and provisional domain generation

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ABSTRACT

Sjögren's disease (SjD) is a systemic autoimmune exocrinopathy with key features of dryness, pain, and fatigue. SjD can affect any organ system with a variety of presentations across individuals. This heterogeneity is one of the major barriers for developing effective disease modifying treatments. Defining core disease domains comprising both specific clinical features and incorporating the patient experience is a critical first step to define this complex disease. The OMERACT SjD Working Group held its first international collaborative hybrid meeting in 2023, applying the OMERACT 2.2 filter toward identification of core domains. We accomplished our first goal, a scoping literature review that was presented at the Special Interest Group held in May 2023. Building on the domains identified in the scoping review, we uniquely deployed multidisciplinary experts as part of our collaborative team to generate a provisional domain list that captures SjD heterogeneity.

Introduction

Sjögren's disease (SjD) is a systemic autoimmune exocrinopathy with key symptoms of dryness, pain, and fatigue [1] that result in a marked reduction in health-related quality of life (HRQoL) [2] and increased healthcare costs [3]. About one third to half of SjD patients experience extra-glandular organ involvement, contributing to high systemic disease "activity". Current disease activity instruments might not encompass all salient disease domains (e.g., brain fog, ocular surface and tear film quality or extra-glandular complications). OMERACT Filter 2.2 is a framework and process to develop core domains that historically have been widely endorsed for use in clinical trials [4,5].

Comprehensive core domain generation using the OMERACT filter has not been done before in SjD. OMERACT requires a broad representation of collaborators from at least three continents for all steps of domain generation and instrument selection. The OMERACT filter will assist in clarifying the domains to be addressed in clinical trials, ensuring broad representation and agreement from the international community. Recognizing the urgent need to establish a core outcome set for utilization in SjD clinical trials, the international SjD community has come together to establish the OMERACT SjD working group dedicated to achieving this objective. The first goal of this working group was to generate domains in SjD using the rigorous OMERACT process. Here, we present provisional SjD domains.

Methods

Forming the working group

NECESSITY is an international consortium of SjD clinicians, researchers, patients, and industrial partners aiming to develop new clinical endpoints in primary SjD. NECESSITY was launched in 2018 thanks to a European Union (EU) grant (IMI: Innovative Medicines Initiative; https://www.necessity-h2020.eu/) to address the need for standardized domains and improved instruments to measure SjD burden. Leaders of the NECESSITY consortium (RS, DC and SB) engaged with OMERACT, an international collaborative effort comprising health care providers/investigators, patient research partners, industry partners, and methodologists to generate data-driven outcome measures for rheumatic conditions [6], to create the SjD OMERACT Working Group. Thus, unifying efforts to identify domains to use in interventional clinical trials and enriching the domain generation process with the lived patient experience. Co-chairs from non-EU continents (SM and MR) joined and then health care providers/researchers, patient representatives, industry representatives and methodologists were invited to participate in the OMERACT SjD Working Group.

Through increased collaboration, the OMERACT Working Group is poised to generate domains reflecting evolving patient experiences, pathogenic insights, and available instrument measurement tools. This collaboration will advance the field through a rigorous methodologic process requiring a broad representation of collaborators from multiple continents for all steps of domain generation. Thus, the SjD OMERACT working group is positioned to formally generate core domains, ultimately creating a core outcome set to be used in SjD clinical trials.

The first step in this joint OMERACT-NECESSITY collaboration is to generate SjD domains by critical collaborators. We presented our progress and future directions at the 2023 OMERACT Special Interest Group (SIG) held in Colorado Springs.

[1] Co-first authors contributed equally to this work.
[2] Co-last authors contributed equally to this work.

PICOC

We developed our Population, Intervention, Comparison, Outcome, and Context (PICOC) to identify a population comprising people with SjD by 2002 AECG [7] or 2016 ACR/EULAR criteria [8] (Fig. 1). Interventions included pharmacologic, non-pharmacologic, and surgical interventions. The control could be placebo or no active treatment. Our outcome was to develop a Core Domain Set with the context of applying this set to randomized controlled trials and controlled trials worldwide.

Generating domains through scoping review and collaboration with expert multidisciplinary groups

Our goal with this step was to identify existing domains used in randomized controlled clinical trials of interventions in SjD. An artificial intelligence (AI) software was developed and tested in the OMERACT process to retrieve and analyze the literature [9,10]. Bibliography BOT (BIBOT) procures and analyzes articles from selected databases using Natural Language Processing (NLP) to extract key concepts from publications. The concept extraction process involves leveraging a latent space organized by MeSH terms, which serve as a structured ontology. The positioning of each newly extracted concept within the ontology is inferred by calculating its distance to the existing terms present in the ontology. This approach empowers BIBOT to conduct concept extraction for a wide range of entities, even those that may not be explicitly defined in the MeSH terms initially. Incorporating BIBOT into the workflow markedly reduces the amount of time required to perform a scoping literature review. This novel approach to literature reviews by incorporating the BIBOT AI tool will accelerate domain generation, addressing a critical need in a timely manner.

We searched for and extracted articles from Medline and EMBASE with search equations derived from our PICOC framework (Fig. 1). We proceeded with the scoping review. The aims were to review all existing SjD-related domains reported in randomized controlled trials of interventions. The included domains retrieved from the selected publications were mapped into core areas, as the OMERACT Filter 2.2 suggests [4,5]. These results were presented during the first Special Interest SjD Group held May 2023 during the OMERACT conference and published in this issue (publication SAR-d-23-00545), informing the development of the core domains set.

Multidisciplinary collaborator consensus domain generation

After the initial domain generation from our scoping literature review, we expanded on our domains with relevant collaborators and experts. One of the major features of SjD is dryness, frequently manifested by ocular and oral dryness. As such, we involved ocular and oral clinicians as experts salient to SjD. As a highly heterogeneous disease, we started domain generation in relevant groups of experts including the following categories: biologic activity, ear/nose/throat (ENT) and oral involvement, ocular involvement, systemic extra-glandular organ involvement, and life impact. Relevant collaborators including patient representatives, clinicians, researchers, immunologists, pathologists, and researchers and industry were included in these domain generating groups.

Results

OMERACT 2023 special interest group

The SjD Working Group currently has 145 total active members. This includes eight patient research partners, 126 health care providers/researchers, 11 industry representatives, and a methodologist (list provided in supplementary material) across 24 countries and spanning six continents. The progress of our work and our future directions are discussed at monthly virtual meetings, held since April 2023.

We held a hybrid SIG in Colorado Springs in May of 2023. Over 26 participants representing more than 7 countries and 4 continents were present at the meeting and contributed to the discussion. The hybrid SIG included patients ($n = 5$), health care providers/researchers ($n = 17$), industry representatives ($n = 3$), and methodologists ($n = 1$). We presented an update on progress in the field of SjD domain generation, the results of our scoping literature review, and the next steps for the SjD working group. We also presented the ongoing work of the NECESSITY consortium.

We began the session by providing an overview of OMERACT and the OMERACT process. We showed our progress to date including Working Group assembly, PICOC generation, and the scoping literature review methods and results. After discussion of this update, we then posed three questions to the group:

Component of PICOC	Description criteria for each component
Population	People with primary Sjögren's Disease (2002 AECG or 2016 ACR/EULAR)
Intervention	Pharmacologic, Non pharmacologic (supportive), and surgical interventions
Control	Placebo or no active treatment
Outcome	Core Domain Set under development
Context (Study types and Setting)	The Core Domain Set will apply to randomized controlled trials, controlled clinical trials, conducted worldwide in the English Language. It will be relevant to patients and the public, researchers, clinicians, policymakers, and guideline developers.

Fig. 1. SjD Working Group PICOC. Our population of interest is primary SjD by 2002 AECG or 2016 ACR/EULAR criteria who participated in a trial with an intervention group (pharmacologic, supportive, or surgical) vs. a placebo or no active treatment arm. Our goal is to generate a core domain set to apply to randomized control trials.

1. The first set of questions focused on the domains identified in the scoping review: a) were they appropriate, b) were they comprehensive, c) should domains include mortality and lymphoma development? The response by the SIG participants indicated that the domains identified in the literature review should be refined and defined further and were not yet saturated. We did not reach a conclusion about whether to include mortality or lymphoma development but acknowledged these were improbable outcomes within the duration of a SjD clinical trial. For OMERACT, mortality is a mandatory domain to include in all clinical trials.
2. The second question asked was what additional qualitative work is necessary to provide a comprehensive SjD picture? SIG participants agreed that the qualitative scoping literature review should be conducted as the next step determining the level of understanding we have of the SjD experience in the literature. Our patient research partners emphasized that life impact domains beyond dryness, pain, and fatigue need to be incorporated into OMERACT domain generation.
3. The third question we asked was how the SIG participants felt about the proposed plan for the working group moving forward and how it relates to current instruments? The consensus was that this question was not relevant to the domain generating portion of OMERACT and that we need to utilize the standardized OMERACT Filter 2.2. The OMERACT filter starts with a methodologically rigorous process to identify domains and then uses an equally rigorous process to match instruments or develop new instruments to measure the identified domains.

During our session, several issues were raised for discussion. Regarding the preliminary results of our scoping review of the literature, the group had concerns about ensuring that the heterogeneity of organ involvement is represented in the broad category of "systemic disease activity". The group clarified that it would be best to break down systemic disease activity into discrete domains (such as pulmonary involvement, renal involvement, etc.). This has been further specified in our scoping review. The group assisted in the optimal mapping of domains identified in the scoping review to the OMERACT 2.2 filter concepts and core areas.

A major discussion outcome of the SIG was the generation of groups with relevant experts focused on generating domains for unique aspects of SjD. These expert groups have the following areas of focus: life impact, oral impact, ocular impact, extra-glandular systemic organ involvement, and biologic activity.

The group also broached the topic of defining domains that will be most important to address in the future. Specifically, whether components of SjD organ involvement will emerge as a mandatory domain as opposed to measures such as lacrimal or salivary flow which traditionally are used to characterize the exocrine dysfunction central to SjD.

There was a spirited debate regarding the work already completed by the NECESSITY consortium and whether ongoing efforts by NECESSITY could be integrated into the OMERACT process. The group agreed that domain generation through the OMERACT 2.2 filter is required. However, previous work for the NECESSITY consortium will be integrated in this process, when appropriate.

Generating domains through scoping review and collaboration with expert multidisciplinary groups

Our scoping review identified 60 randomized controlled trials (RCTs) yielding 41 domains. These domains were mapped to the following major concept areas: pathophysiology/manifestations/abnormities ($n = 32$), life impact ($n = 6$), longevity ($n = 1$), and societal resource use ($n = 2$). Using our scoping literature review (see article in this issue of Seminars: SAR-d-23-00545) to generate our initial working domains, we moved to expert consensus to further expand these initial domains. Five expert consensus groups met at least once to generate these domains: the ocular impact group ($n = 19$), the ENT/oral impact group ($n = 24$), extra-glandular organ involvement ($n = 38$), biological parameters group ($n = 19$), and life impact group ($n = 38$). We discussed the generated domains at one combined group session with the entire SjD OMERACT Working Group.

We generated an expansive provisional list of domains related to the pathophysiology of SjD. This included a total of 31 provisional target domains (Table 1) and 47 target domain components (Supplemental Table A).

The life-impact group distilled their domains to six target domains (dryness, fatigue, mental or emotional health, pain, physical function, and social participation). The biologic activity group identified three target domains for biologic activity (B cell activity, other immune cell disturbance, and soluble mediators/inflammatory markers). The ENT/oral group had four target domains (ear involvement, oral health, oropharyngeal dryness, and salivary gland involvement). The ocular involvement group identified two main pathophysiologic target domains including extra-glandular and glandular ocular involvement. The systemic extra-glandular organ involvement group had 15 target domains (articular, central nervous system involvement, constitutional signs, cutaneous, gastrointestinal involvement, global systemic activity, gynecologic/urinary/reproductive involvement, hematological involvement, hepatobiliary involvement, lymphadenopathy/malignancy, muscular involvement, peripheral nervous system involvement, pulmonary involvement, renal involvement, and vascular/vasculopathy).

Discussion

Since the start of this process in February 2023, the OMERACT SjD Working Group has achieved marked progress in understanding major limitations in the current instruments to measure HRQoL and disease activity in SjD. Following OMERACT methods [5,6], we have completed

Table 1
Provisional target domains.

Life Impact	Dryness Fatigue Mental or emotional health Pain Physical function Social participation
Resource Use	Direct costs
Pathophysiological Manifestations	Articular involvement B cell activity CNS involvement Constitutional signs Cutaneous involvement Ear involvement GI involvement Global systemic activity Gyn/urinary/reproductive involement Hematological involvement Hepatobiliary involvement Lymphadenopathy/malignancy Muscular involvement Ocular (dys)function-glandular Ocular (dys)function-extraglandular Oral health Oropharyngeal dryness Other immune cell disturbance PNS involvement Pulmonary involvement Renal involvement Salivary gland involvement Soluble mediators/inflammatory markers Vascular/vasculopathy

CNS=central nervous system; GI=gastrointestinal; Gyn=gynecologic; PNS=peripheral nervous system.

a scoping literature review and will now need to create a core domain set for SjD that incorporates input from multiple collaborators. We were encouraged at our recent SIG meeting by the community's robust engagement. After careful consideration of the feedback provided by our SIG, we generated focused groups for expert and collaborator domain generation to reflect the heterogeneity of SjD. We report an expansive list of SjD domains and are moving toward completing our qualitative work as a next step (Fig. 2).

Our first qualitative goal is to understand the existing landscape of qualitative research in SjD. To accomplish this, we will perform a scoping qualitative literature review with BIBOT, akin to our review of RCTs except without the limitation of trial type. This innovative use of BIBOT software will reduce the time investment that is typically required for a qualitative scoping review, allowing the SjD SIG to continue to progress through the OMERACT process efficiently.

Conclusion

There is a great need to generate a comprehensive picture of the burden SjD imposes on our patients. To address this need, we are using the methodologically rigorous OMERACT process to generate a core domain set with input from key collaborators across the world. This work represents the first critical step that has been taken towards identifying the core domains for SjD to be used in interventional clinical trials.

Declaration of competing interest

Valerie Devauchelle reports receinving funds for consulting to Novartis, Abbvie, Fresenius Kabi.

Divi Cornec declares no personal financial competing interests and received research funding from Novartis and GSK.

Benjamin A. Fisher has undertaken consultancy for Novartis, BMS, Servier, Galapagos, Roche, UCB, Sanofi and Janssen, and received grant/research support from Janssen, Celgene, Galapagos, Servier.

Alberta Hoi reports receiving research funding from AstraZeneca, Bristol-Myers Squibb, Novartis, Janssen.

Chiara Baldini reports receiving funds for consulting to GSK, Novartis and Horizon, honoraria for educational events from GSK and Sanofi, support for attending meetings from Abbvie and Bristol-Myers Squibb.

WF Ng has consulted for Novartis, GlaxoSmithKline, Abbvie, BMS, Sanofi, MedImmune, Resolves Therapeutics, Janssen and UCB.

Simon Bowman receiving funds for consulting from Bristol-Myers Squibb, Iqvia, Janssen, Kiniksa, Novartis, Otsuka-Visterra. His-salary is part funded by the Birmingham Biomedical Research Centre, Birmingham, UK.

Karina Torralba reports receiving funds for consulting to Horizon, AstraZeneca, Janssen; for contracted research work with Bioclinica; for clinical trial funding from Novartis, AstraZeneca, GlaxoSmithKline, Amgen.

Athena Papas declares grant funding from Novartis and Horizon; advisory board for Novartis.

Ionut Pintilie reports receiving funds for consulting to Abbvie, Novartis, Pfizer, Sandoz, Ewopharma, KRKA, Stada, Boehringer Ingelheim, MagnaPharm, MSD.

Xavier Mariette declares consulting fee from Astra Zeneca, BMS, Galapagos, GSK, Novartis, and Pfizer.

Maria Antonietta D'Agostino, MD, PhD Speakers, or consultant fees from Amgen, Abbvie, BMS, Novartis, Galapagos, UCB, Pfizer, Lily, Janssen.

Alan Baer reports receiving funds for consulting to Bristol-Myers Squibb and iCell Gene Therapeutics.

Blake M. Warner declares research funding and material transfer agreements with Pfizer, Inc., and Mitobridge, Inc.

Soumya D. Chakravarty is an employee of Janssen Scientific Affairs,

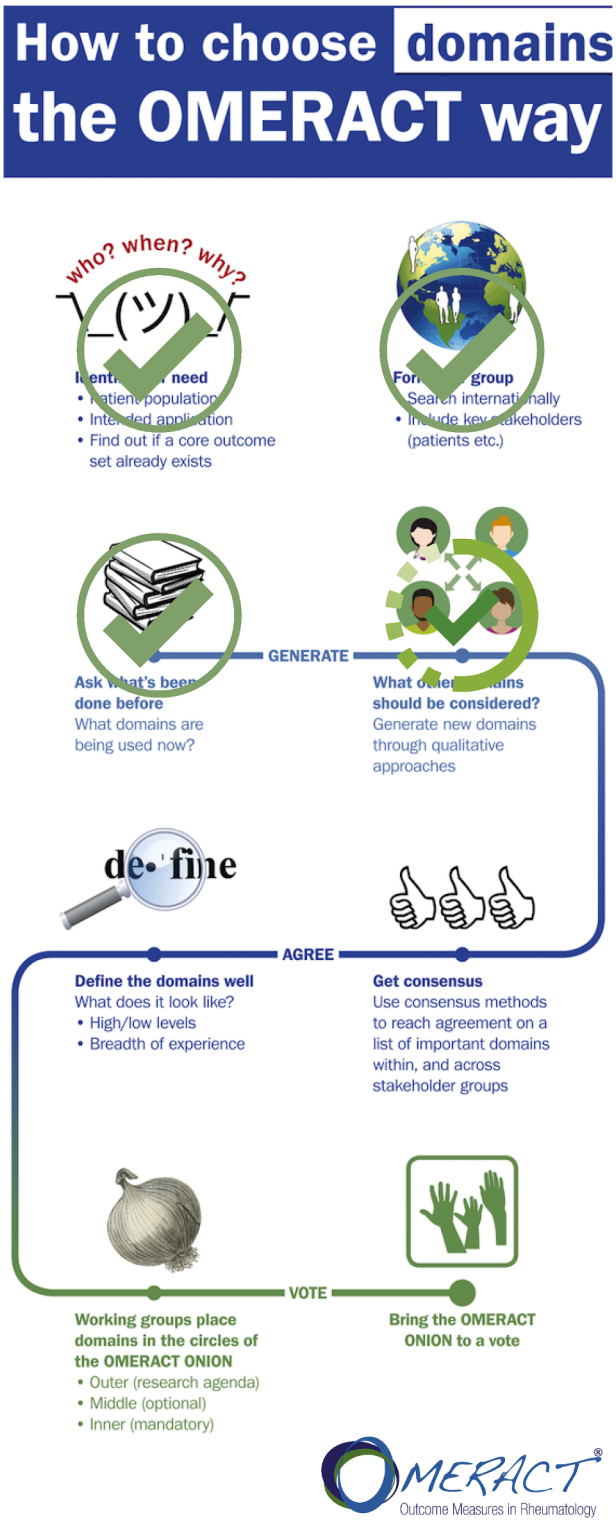

Fig. 2. SjD Working Group Domain Generation Progress. SjD Working Group Domain Generation Progress. We have completed our scoping literature review and domain generation through expert consensus. We are planning our qualitative work. Our next steps include generation of domains and Delphi consensus. Image adapted from the OMERACT Handbook, version 2.1 Updated April 1st 2021; Available from: https://omeracthandbook.org.

LLC, and owns stock or stock options in Johnson & Johnson, of which Janssen Scientific Affairs, LLC is a wholly owned subsidiary.

Nevsun Inanc reports claims to have received speakers fee from Novartis, Abbvie, Pfizer, UCB, Eli-Lilly and consultancy fee from Abbvie, UCB, Eli-Lilly.

Vibeke Strand reports being a founding member of the executive committee of Outcome Measures in Rheumatology (OMERACT) [1992 – present], an international consensus organization that develops and validates outcome measures in rheumatology randomized controlled trials and longitudinal observational studies and has received arms-length funding from as many as 36 sponsors.

Md Yuzaiful Md Yusof has received speaker fees from Roche and Novartis and consultancy fees from Aurinia Pharmaceuticals and UCB.

Suzanne Arends declares consultancy fees from Argenx and Novartis.

Anas Alexis Benyoussef is a consultant for Horus Pharma and Quantel Medical.

Sharmila Masli is a consultant for Stellular Bio Inc. and Proteris Biotech.

Maureen Rischmueller has undertaken consultancy/speaker engagements for AbbVie, Boehringer Ingelheim, Janssen Global Services, Novartis, Pfizer and Sandoz, and received grant/research support from AbbVie, Amgen, AstraZeneca, BMS, GSK, Janssen, Lilly, Novartis, Pfizer, Servier and UCB.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.semarthrit.2024.152378.

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