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Patient outcomes in longitudinal observational studies (POLOS) of rheumatoid arthritis: Determining the OMERACT core domain set

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ABSTRACT

Objective: To define and select rheumatoid arthritis (RA)-specific core domain set for Longitudinal Observational Studies (LOS) within the Outcome Measures in Rheumatology (OMERACT) framework.
Methods: A three-round online Delphi exercise, including patient research partners (PRPs) and other community partners in healthcare, was conducted. Domains scored 7–9 (i.e., critically important to include) by ≥ 70 % of participants in both groups were included. Items were consolidated in a subsequent dedicated meeting.
Results: Nineteen domains scored ≥ 70 % consensus in both groups. The focus group refined these into a list of twelve domains.
Conclusion: The achieved consensus will inform the next steps of developing the core domain set for LOS in RA.

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Introduction

Longitudinal observational studies (LOS), which involve the repeated collection of data from the same individuals over a specified period, have proven instrumental in understanding the impact of rheumatoid arthritis (RA). They provide comprehensive insights into the trajectory of the disease and its multifaceted effects on patients [1]. However, the need for more standardization in outcome measurement presents a challenge in harmonizing the wealth of data generated by these studies. It has been widely accepted that relevant outcomes in LOS may vary from those gathered in randomized controlled trials (RCTs) [2]. The experimental nature of RCTs often requires relatively short-term outcomes to assess drug efficacy, while LOS, being observational, can focus on broader, long-term outcomes related to e.g., the natural history of the disease or therapeutic safety. Establishing a core set of domains specifically tailored for LOS in RA is essential in bridging this gap. By enhancing the consistency of data collection and analysis across studies, a core outcome set would enable more effective comparisons, contribute to the robustness of evidence, and pave the way toward more patient-centric care and treatment strategies in RA.

The drive to establish standardized outcomes in LOS gave rise to the Patient Outcomes in Longitudinal Observational Studies (POLOS) Working Group under the auspices of the Outcome Measures in Rheumatology (OMERACT) initiative [3]. Developing a core outcome set requires two consecutive phases: selecting the core domain set and the core measurement set. The OMERACT Filter 2.1 methodology, that follows a three-stage framework is employed [4]. Initially, candidate domains are generated through scoping reviews and qualitative work. Then, a consensus process is conducted to obtain agreement on domains from the patients and other community partners/collaborators involved. Finally, formal voting on the OMERACT Onion occurs, categorizing domains into layers based on their importance. In the second phase, an evidence-based framework guides the assessment of outcome measurement instruments for inclusion in a core measurement set [5].

Preparatory work included a systematic review to identify domains used in LOS [6], a qualitative analysis of important domains reported by patients and caregivers [7], and the categorization of domains following the OMERACT Filter 2.1 framework [8,9]. These domains set the ground for the current study, aimed at consolidating consensus on candidate core domains among the OMERACT community.

Methods

Study design and participants

A three-round Delphi survey evaluating domains was developed using the OMERACT consensus methodology [10]. Each domain was evaluated based on its importance for inclusion in the core domain set.

Participants were included if they were self-identified patients with RA, and healthcare providers or researchers with rheumatology expertise. The ability to engage with the survey digitally was necessary, while there were no geographical limitations for participation. Participants were recruited through the OMERACT network, lists of researchers participating in registries obtained from previous search [2,6], and LOS in rheumatology around the world from contacts, direct mailing to patients and clinicians' groups, and posts on social media (Facebook and LinkedIn of steering group members). Participants were categorized in two groups: patient research partners (PRPs) and all other community partners, including healthcare providers, researchers, policymakers, industry professionals, and payers. Participants who self-identified as patients in the survey were designated as PRPs, a classification supported by their affiliation with the OMERACT network and their presumed active engagement in the research process.

Study procedures

The Delphi process consisted of three consecutive rounds: the first round commenced in March 2022, the second round launched in April 2023, and the third round concluded in July 2023. Potential participants received an email with a clear explanation of the study's objectives and guidelines, as well as an invitation and link to the survey (DelphiManager) [11]. Four weeks were allowed for responses to each round, with reminders and longer response periods to reach a minimum sample of 200 PRPs and 200 other collaborators.

In each of the rounds, participants were asked to rate each domain based on a 1–9 scale, which corresponded to their perceived importance of the domain for the core set, from 1 (*not important*) to 9 (*critically important*). After round 1, participants were provided with the results for each specific domain by group, and a reminder of their individual answer in the previous round. Any additional comments or thoughts on their decisions were also gathered through open comment fields. A domain was accepted for inclusion in the core set if it was deemed *critically important* (i.e., 7 to 9 scores) by at least 70 % of participants from each group separately in the first two rounds that the domain was assessed. Moreover, the group decided that if an item was deemed *critically important* (i.e., 7 to 9 scores) by at least 70 % of patients but not by other collaborators, it was also included. Domains were removed from consideration if $\geq$ 70 % of participants from both patients and community partners groups scored them as *not important* (i.e., equivalent to a score of 1 to 3).

The initial questionnaire in round 1 requested participants to assess 57 target domains, from 8 broad domains, mapped in 4 core areas (Pathological Manifestations, Life Impact, Death/ Lifespan, Societal/ Resource use) (Supplementary Table 1). Each Delphi round sparked an online discussion among the members of the OMERACT POLOS-RA Working Group on the results, prompting amendments to the questionnaire for the next round.

At the 2023 OMERACT gathering in Colorado Springs, a Special Interest Group (SIG), specifically dedicated to LOS was convened. The meeting comprised a multidisciplinary team of patient research partners (PRPs), healthcare professionals, academics, and methodologists. The collective aim was to select and refine domains that hold significance for all community partners. During this session, findings from the initial two Delphi surveys were critically evaluated and deliberated upon.

After the final Delphi round, a virtual meeting was held with a focus group comprising six PRPs and two rheumatologists. The aim of this was to reduce the voted items into an acceptable number of candidate domains that should be included in the LOS core domain set. Following these discussions, a preliminary set of items was proposed.

The study was approved by the Institutional Review Board (IRB) of the primary research site, the University of Texas MD Anderson Cancer Center. Upon receiving IRB approval, participant consent was implicitly granted through their engagement in the digital survey, which followed a thorough review of the informational details of the study.

Results

In total, 442, 268, and 212 participants took part in the first, second, and third round of the Delphi survey, respectively. The participants were mostly PRPs (287, 159 and 123, respectively) and other collaborators (155, 109 and 89, respectively). *Other collaborators*, beyond rheumatologists (63.2 %), included mainly researchers (10.3 %), allied health professionals including physiotherapists and occupational therapists (7.1 %), or nurses (5.8 %).

Overall, 335 (76 %) participants were female, 105 (24 %) were male, 1 (< 1 %) identified as non-binary and 1 (< 1 %) preferred not to answer. Ages ranged from 20 to 90 years, with most participants ranging from 60 to 70 years and residents of 37 different countries. Comparing second-round completers (n = 268) with second-round non-completers (n = 174) among those that completed the first round, no significant

differences emerged in age, with the range of "60–69 years" being the most common (completers 29.9 %, non-completers 33.3 %, $p = 0.1951$), gender (females dominant in both, completers 73.5 %, non-completers 79.3 %, $p = 0.4069$), or background, with PRPs being the most frequent group (completers 52.6 %, non-completers 67.2 %, $p = 0.3716$).

Results of the final round, stratified by PRPs and other collaborators, are shown in Table 1. After the initial round, participants suggested the inclusion of 58 additional domains. These new domains were assessed to ensure they were not repeated or subsumed under another category. Upon refinement, 14 of these suggestions were ultimately chosen for addition as new domains (Supplementary Table 2).

After the final Delphi round, consensus was achieved for acceptance of nineteen domains across the four core areas.

Pathological manifestations: Nine domains reached consensus on acceptance; joint pain, joint stiffness, joint swelling, fatigue, overall pain, comorbidities, such as cardiovascular/stroke/ hypertension, infections, or osteoporosis, and drug adverse events.

Life impact: Four domains reached consensus; function (walking/ using stairs/going out), dependency on others, health related quality of life, and remission status.

Death/lifespan: Two domains reflected the core area of death/lifespan, namely disease-specific mortality, and treatment-related mortality.

Societal/resource use: Four domains belonged to this area; healthcare utilization, direct costs, indirect costs, and out-of-pocket costs.

Notable discordance was found between PRPs and other collaborators across various domains. Seven and ten domains were discrepant between groups in the first and second rounds, respectively. In the final round, 5 domains were accepted ($\geq$ 70 %) by other collaborators but not PRPs, including cancer (85 % vs. 63 %), grooming/personal hygiene (89 % vs. 67 %), performance: absenteeism/work performance/presenteeism (72 % vs. 43 %), loss of income (78 % vs. 62 %) and overall mortality (92 % vs. 65 %). Domains accepted by PRPs but not by other collaborators were satisfaction with treatment (85 % vs. 69 %), and future financial concerns (71 % vs. 42 %).

In the process of finalizing the domains, a 'winning and binning' approach was employed, whereby certain domains were prioritized ('winning'), while others were consolidated or redefined for clarity and comprehensiveness ('binning') (Table 2). The joint involvement domain was defined to incorporate previously separate categories of joint pain, joint stiffness, and joint swelling. The comorbidities domain was proposed to include infections, cancer, cardiovascular events, as well as osteoporosis and fractures. The domain of therapeutic adverse events-specified to be assessed only in drug-related studies- was renamed under the term 'safety'. The function domain was proposed to encompass activities of daily living, such as grooming/dressing/personal hygiene and walking/using stairs/going out. The independency domain evolved from the earlier dependency on others category. Additionally, the domain financial and resource impact was proposed, covering a broad range of economic aspects, from future financial concerns to healthcare utilization, direct and indirect costs, as well as out-of-pocket expenses.

Discussion

This project used a consensus-driven approach to standardize domains in LOS for RA. We established a preliminary core set of domains through an iterative Delphi process. Two groups of participants were involved –PRPs and other community partners. Over three rounds of voting, consensus was reached on 19 core domains that effectively capture the long-term outcomes of RA from various perspectives. Discrepancies between PRPs and other community partners underscored the need for further refinement of the outcome set, especially in areas such as joint stiffness, satisfaction with treatment, and financial burden.

In the 2023 OMERACT POLOS SIG meeting, handling discrepant domains was a key focus. The consensus in the meeting was that domains voted as essential by $\geq$ 70 % of PRPs should be included in the core set, advocating for the patient-centric approach of this research. Moreover, the importance of examining qualitative data was underscored to understand these discrepancies better. For example, personal hygiene was noted as a possible source of discrepancy between groups, as patients may adapt to challenges in this area over time, leading to their lower prioritization, while those not living with the disease saw it as a relevant domain.

During the meeting, the proposition of consolidating —or binning— certain domains was also discussed. There was a general agreement that some domains, like grooming, could be effectively merged into broader categories, such as physical functioning. Mortality-related domains and cost categories, inclusive of health utilization, were also proposed for consolidation. Further, it was suggested that some grey area domains might be subsumed under health-related quality of life, thereby streamlining the core set. The possibility of associating infections and cancer with drug adverse events was also debated, though the classification of these as comorbidities was acknowledged. In sum, the consensus leaned towards domain merging, but emphasized that any merging must align with the initial definitions, thus maintaining the validity of the core domain set and its usefulness for the subsequent selection of instruments [12]. The idea of consolidating domains was broadly accepted, with an overwhelming 96 % in favor of domain lumping, to be done after the third Delphi round.

Therefore, the merging of voted items followed in a successive stage in the dedicated online meeting of the focus group facilitated with the assistance of PRPs. The meeting ensured that the lumping was conducted from a patient perspective, with attention to detail, and preserving the nuanced insights obtained from the Delphi rounds. Twelve selected domains were proposed in this session. During the meeting, the process of consolidating domains was completed, including merging some domains and the renaming of others, to provide clearer insights for researchers, while simultaneously capturing the breadth of patients' experiences and challenges.

It is important to recognize that certain constraints were present in our study. Despite the robustness of the three-round Delphi exercise, the interaction between participants was limited to survey responses, without the opportunity for a collective discussion which could have further enriched the data with nuanced insights and consensus. A more consistent engagement with PRPs throughout the entire Delphi process could have provided additional depth and context to the findings. Moreover, detailed educational background information of the patient participants was not collected, and we could not address if there was some sociodemographic factor that impacted the responses. Future studies should prioritize including patients with varying levels of health literacy and socioeconomic status while adapting research methodologies to be more accessible and less burdensome. Another limitation of our study includes the aggregation of the group of other collaborators into a single group, which was not subdivided further due to the low number of respondents in each category, yielding a heterogeneous group of participants. Besides, a significant reduction in participant numbers was encountered from the first to the third round, which may have been influenced by the extensive number of items, leading to response fatigue. Iterations of this research could benefit from incorporating a preliminary patient-led item reduction phase to mitigate this.

Further steps will include developing definitions for the twelve candidate core domains and sorting them into the OMERACT three onion layers according to their relevance. The Delphi results, together with the observations during the POLOS SIG meeting at OMERACT 2023 and the focus group meeting, are valuable steps in the quest to establish the most relevant domains to yield a comprehensive, patient-centric core set for RA in LOS.

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Declaration of generative AI and AI-assisted technologies in the writing process

During the preparation of this work the author(s) used ChatGPT in order to improve language and readability. After using this tool/service, the author(s) reviewed and edited the content as needed and take(s) full responsibility for the content of the publication.

CRediT authorship contribution statement

Diego Benavent: Writing – original draft, Data curation, Investigation. **Loreto Carmona:** Conceptualization, Supervision, Methodology, Writing – review & editing. **Maria A. Lopez-Olivo:** Conceptualization, Methodology. **Catherine L. Hill:** Methodology, Writing – review & editing. **Tiffany Westrich-Robertson:** Writing – review & editing. **Niti Goel:** Methodology, Writing – review & editing. **Vibeke Strand:** Writing – review & editing. **Beverley Shea:** Methodology, Writing – review &

Table 1
Results for each domain in final round of the Delphi survey

	PRP		Other collaborators	
	1-3	7-9	1-3	7-9
Pathological Manifestations				
Joint pain#	3 (2)	134 (83)	0 (0)	107 (96)
Overall pain*	2 (2)	106 (86)	2 (2)	76 (85)
Joint stiffness#	2 (1)	122 (76)	1 (1)	77 (70)
Joint swelling#	8 (5)	117 (73)	0 (0)	104 (94)
Joint deformity/nodules/ appearance*	6 (5)	78 (63)	5 (6)	62 (70)
Fatigue#	3 (2)	115 (71)	1 (1)	78 (70)
Malaise	10 (8)	45 (37)	17 (19)	7 (8)
Cognitive fog	15 (12)	47 (38)	29 (33)	2 (2)
Sleep disturbance	4 (3)	80 (65)	7 (8)	27 (30)
Appetite	33 (27)	12 (10)	44 (49)	2 (2)
Low libido*	57 (46)	12 (10)	29 (33)	1 (1)
Physical fitness*	3 (2)	76 (62)	7 (8)	25 (28)
Corticosteroids use *	16 (13)	60 (49)	3 (3)	57 (64)
NSAIDs use*	16 (13)	54 (44)	6 (7)	31 (35)
Infections	7 (6)	87 (71)	1 (1)	76 (85)
Cancer	18 (15)	77 (63)	-	76 (85)
Cardiovascular/stroke/ hypertension#	15 (9)	115 (71)	1 (1)	86 (78)
Osteoporosis/fractures	10 (8)	85 (70)	0 (0)	76 (85)
Weight change	16 (13)	33 (27)	11 (12)	8 (9)
Consequences of surgery	13 (11)	60 (49)	10 (11)	34 (38)
Drug adverse events#	10 (6)	126 (78)	2 (2)	96 (87)
Fertility	57 (46)	15 (12)	9 (10)	24 (27)
Pregnancy complications	54 (44)	21 (17)	6 (7)	56 (63)
Lung*	15 (12)	75 (61)	1 (1)	53 (60)
Other: kidney, skin problems, eyesight problems…*	8 (7)	81 (66)	4 (5)	34 (38)
Life Impact				
Grooming/dressing/personal hygiene	6 (5)	82 (67)	0 (0)	78 (89)
Housework/cooking	5 (4)	45 (37)	3 (3)	61 (69)
Transportation/commuting/driving	9 (7)	64 (53)	3 (3)	58 (66)
Sexual function	41 (34)	20 (16)	2 (2)	23 (26)
Walking/using stairs/going out#	7 (4)	119 (75)	0 (0)	92 (84)

(*continued on next page*)

Table 1 (*continued*)

	PRP		Other collaborators	
	1-3	7-9	1-3	7-9
Dependency on others	9 (7)	85 (70)	0 (0)	78 (89)
Anxiety	7 (14)	62 (51)	1 (1)	36 (41)
Depression	16 (13)	67 (55)	1 (1)	45 (51)
Stress	15 (12)	58 (48)	6 (7)	14 (16)
Loneliness	18 (15)	41 (34)	8 (9)	8 (9)
Helplessness	17 (14)	54 (44)	8 (9)	16 (18)
Anger	29 (24)	36 (30)	15 (17)	3 (3)
Unhappiness/lack of enthusiasm	18 (15)	42 (34)	9 (10)	7 (8)
Self-image/Appearance	17 (14)	37 (30)	8 (9)	8 (9)
Work loss/demotion/lack of promotion	23 (19)	50 (41)	1 (1)	54 (61)
Feeling valuable to society*	12 (10)	45 (37)	10 (11)	18 (21)
Coping*	5 (4)	75 (62)	5 (6)	40 (46)
Self-efficacy*	10 (8)	58 (48)	3 (3)	42 (48)
Performance: absenteeism/work performance/presenteeism	25 (21)	53 (43)	1 (1)	63 (72)
Job satisfaction	27 (22)	25 (21)	8 (9)	3 (3)
Adaptability (flexibility, work from home, adaptations, training)	28 (23)	42 (34)	7 (8)	11 (13)
Intimacy/sexual relations	36 (30)	31 (25)	3 (3)	16 (18)
Family role: Establishing partner relationships/marriage	21 (17)	53 (43)	3 (3)	26 (30)
Spousal/partner support	20 (16)	71 (58)	7 (8)	20 (23)
Family role: Childbearing	47 (39)	21 (17)	5 (6)	19 (22)
Family role: take care/supporting family	19 (16)	50 (41)	4 (5)	19 (22)
Ability to care for pets	28 (23)	33 (27)	37 (42)	5 (6)
Burden to others/dependency	8 (7)	81 (66)	3 (3)	43 (49)
Interactions with others/not being able to make new friends	16 (13)	33 (27)	8 (9)	4 (5)
Leisure activities	12 (10)	39 (32)	2 (2)	7 (8)
Hobbies	13 (11)	34 (28)	9 (10)	4 (5)
Studying	33 (27)	18 (15)	10 (11)	10 (11)
Overall quality of life*	5 (4)	106 (87)	0 (0)	84 (96)
Satisfaction with treatment*	3 (3)	104 (85)	2 (2)	61 (69)
Remission status*	6 (5)	90 (74)	0 (0)	73 (83)
Loss of income	16 (13)	75 (62)	1 (1)	69 (78)
Financial toxicity	21 (17)	68 (56)	7 (8)	42 (48)
Future financial concerns	14 (12)	86 (71)	9 (10)	37 (42)
Financial dependency	15 (12)	80 (66)	4 (5)	54 (61)
Death/Lifespan				

(*continued on next page*)

Table 1 (*continued*)

	PRP		Other collaborators	
	1-3	7-9	1-3	7-9
Overall mortality	6 (5)	79 (65)	1 (1)	82 (92)
Disease-specific mortality[#]	8 (5)	127 (80)	3 (3)	99 (90)
Treatment-related mortality[#]	5 (3)	135 (85)	2 (2)	103 (94)
Societal/Resource use				
Healthcare utilization[#]	1 (1)	127 (80)	0 (0)	89 (82)
Direct costs[#]	2 (1)	129 (81)	0 (0)	82 (75)
Indirect costs[#]	3 (2)	116 (73)	0 (0)	76 (70)
Out of pocket costs[#]	1 (1)	125 (79)	1 (1)	79 (73)

Results are expressed as n (%), in which the % represents the total participants in the subgroup voting to the specified range. PRP: Patient Research Partners. *Included from the second round onwards. [#]Consensus achieved in the second round. Color code: Green: consensus on acceptance (≥70%) in both groups; Yellow: consensus in only one of the groups.

Table 2
Domains consolidated by the focus group

New domain	Included previous categories/items
Joint Involvement	Joint pain, Joint stiffness, Joint swelling
Overall pain	Overall pain
Fatigue	Fatigue
Comorbidities outcome	Infections, cancer, cardiovascular/stroke/hypertension, osteoporosis/fractures
Safety*	Drug adverse events
Function	Grooming/dressing/personal hygiene, Walking/using stairs/going out, and participation in social, leisure, work and educational activities
Independency	Dependency on others
Health related quality of life	Overall health related quality of life
Satisfaction with treatment	Satisfaction with treatment
Remission Status	Remission status
Mortality	Disease-specific mortality, treatment-related mortality
Financial and resource impact	Future financial concerns, Healthcare utilization, Direct costs, Indirect costs, out-of-pocket costs

* Only to be assessed in therapeutic studies

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Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

DB: Speakers bureau: Janssen, UCB, MSD, Abbvie, Galapagos, Lilly. Research Grant: Novartis; LC: Participation on a Data Safety Monitoring Board or Advisory Board: Lilly, Hospital Clínico San Carlos. EULAR Chair of Advocacy; MALO: Grants: National Cancer Institute, Rheumatology Research Foundation, Duncan Family Institute for Cancer Prevention and Risk Assessment. Consulting fees: American Cancer Society; MdW: Speakers bureau: UCB. Convenor EULAR study group for collaborative research; VS: Founding member of the executive committee of OMERACT [1992 – present]; DBB: Support for attending meetings: Erna Hamilton Foundation. Grants: PhD Scholarships from Odense University Hospital and from the Faculty of Health Sciences; Peter Böhm: Support for attending meetings and/or travel: EULAR, FOREUM. MSA: Consulting fees: Pfizer, Eli Lilly, Syneos Health and Celgene. The rest of the authors declare no conflicts of interest.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.semarthrit.2023.152343.

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