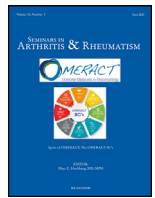




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## Endorsement of the OMERACT core domain set for shared decision making interventions in rheumatology trials: Results from a multi-stepped consensus-building approach

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Abbreviations: OMERACT, outcome measures in rheumatology; SDM, shared decision making; PRPs, patient research partners

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<https://doi.org/10.1016/j.semarthrit.2021.03.017>

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## ARTICLE INFO

### Keywords:

OMERACT

Shared decision making

Core domain set

## ABSTRACT

**Objective:** To gain consensus on the Outcome Measures in Rheumatology (OMERACT) core domain set for rheumatology trials of shared decision making (SDM) interventions.

**Methods:** The process followed the OMERACT Filter 2.1 methodology, and used consensus-building methods, with patients involved since the inception. After developing the draft core domain set in previous research, we conducted five steps: (i) improving the draft core domain set; (ii) developing and disseminating whiteboard videos to promote its understanding; (iii) conducting an electronic survey to gather feedback on the draft core domain set; (iv) finalizing the core domain set and developing summaries, a plenary session video and discussion boards to promote its understanding; and (v) conducting virtual workshops with voting to endorse the core domain set.

**Results:** A total of 167 participants from 28 countries answered the survey (62% were patients/caregivers). Most participants rated domains as relevant (81%–95%) and clear (82%–93%). A total of 149 participants ( $n = 48$  patients/caregivers, 101 clinicians/researchers) participated in virtual workshops and voted on the proposed core domain set which received endorsement by 95%. Endorsed domains are: 1- Knowledge of options, their potential benefits and harms; 2- Chosen option aligned with each patient's values and preferences; 3- Confidence in the chosen option; 4- Satisfaction with the decision-making process; 5- Adherence to the chosen option and 6- Potential negative consequences of the SDM intervention.

**Conclusion:** We achieved consensus among an international group of stakeholders on the OMERACT core domain set for rheumatology trials of SDM interventions. Future research will develop the Core Outcome Measurement Set.

**Clinical significance:** Prior to this study, there had been no consensus on the OMERACT core domain set for SDM interventions. The current study shows that the OMERACT core domain set achieved a high level of endorsement by key stakeholders, including patients/caregivers, clinicians and researchers.

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## Introduction

Shared decision making (SDM) is central to patient-centered care since it facilitates inclusion of patient values, preferences, and circumstances in decision-making, thus helping patients participate in making decisions in a meaningful way [1,2]. In the last decade, there has been increasing interest in SDM in rheumatology [3] and an imperative to use SDM to achieve optimal care [4–7]. To help prepare individuals to participate in the SDM process, various SDM interventions have been developed in rheumatology, including patient decision aids [8]. Despite trials of patient decision aids in rheumatology, as well as the incorporation of SDM into rheumatology guidelines, there remains a lack of consensus among stakeholders (e.g., clinicians, patients and researchers) on how to standardize measurement of the effectiveness and safety of SDM interventions [8,9]. Another research group has identified domains to assess the effectiveness of patient decision aids [10]. However, most concern the SDM process, and only one assesses an outcome (i.e., improved match between chosen option and features that matter most to the informed patient).

The goal of the Outcome Measures in Rheumatology (OMERACT) SDM working group is to develop and gain consensus on a core domain set of outcomes for trials of SDM interventions. The working group includes OMERACT patient research partners (PRPs), as well as researchers and clinicians from around the world. These stakeholders participated in all steps of the project. Our working group conducted a systematic review and nominal group process at OMERACT 2014 to develop the draft core set [11]. Then, we conducted an electronic Delphi survey to refine domains of the draft core set, followed by a workshop to vote on the draft core set at OMERACT 2016 [12]. Since the draft core domain set failed to achieve the 70% agreement required for endorsement at the OMERACT 2016 workshop, we prepared a White Paper and conducted interviews to clarify the domains [13]. This led to the development of a final White Paper and an improved draft core domain set, comprised of five mandatory domains to assess in trials of SDM interventions. Recommendations from this work included further dissemination of the draft core domain set to increase its understanding and facilitate consensus-building.

The overall aim of this final phase of the consensus-building process was to gain consensus and endorse the OMERACT core domain set for rheumatology trials of SDM interventions.

## Material and methods

### Study design

We conducted a study with five steps, using consensus-building methods grounded in a patient-oriented approach [14], with all stakeholders including patients involved from the inception. The process followed the OMERACT Filter 2.1 methodology for the selection

of core domain sets [15–17] and OMERACT recommendations for PRP involvement [18]. The first four steps aimed to refine, clarify and promote understanding of the core domain set among key stakeholders. The fifth step aimed to obtain endorsement of the core domain set. We obtained ethics approval from the Children's Hospital of Eastern Ontario Research Ethics Board (REB#16/07X). The research process is detailed below.

### Steps

#### *Improving the draft core domain set*

The working group reviewed findings from the interviews [13] and other previous steps to ensure the accuracy and clarity of the draft core domain set.

#### *Developing and disseminating white-board videos*

To ensure the draft core domain set was presented in a clear, concise and appealing manner to all stakeholder groups, the group developed two white-board videos with feedback from 42 working group members (including nine PRPs) to explain the SDM process, outcomes and the draft core set. These videos aimed to summarize information from the White Paper in a concise and visual manner. Videos were posted on YouTube, social media and the OMERACT website to promote understanding of the core domain set and to encourage individuals to participate in next steps.

#### *Conducting an international survey*

An electronic survey, co-developed with clinicians and PRPs from our working group, was administered to gather additional feedback on the clarity and relevance of the draft core domain set (February 2020). Eligible respondents included individuals with a rheumatic condition and their caregivers, rheumatology clinicians, and researchers involved in rheumatology or SDM research. The survey was created in REDCap, and the link was sent via e-mail to members of the OMERACT network and other rheumatology organizations (see acknowledgements), and posted on the OMERACT website and on social media.

The survey questionnaire included an introduction with the goals of the research project, as well as links to the white-board videos and White Paper. Respondents were advised to watch the videos, and recommended to read the White Paper for detailed information. The survey asked respondents to rate the clarity and relevance of each outcome domain using a 9-point Likert scale, and asked if they wished to make modifications. For each outcome domain, the number of respondents and proportion of responses with a rating of 7 to 9 (i.e., very clear and relevant) were summarized for each stakeholder group and for the total sample. Domains were considered clear and relevant if at least 70% of respondents rated them from 7 to 9.

### *Finalizing the core domain set and developing evidence summaries and online discussion boards*

The working group reviewed modifications suggested in the survey. The final core domain set was presented in the OMERACT “onion” [15], which shows domains that are mandatory in all trials of SDM interventions, indicated by their high relevance in qualitative work and surveys (i.e., at least 70% of respondents rating them from 7 to 9, and fewer than 15% rating them from 1 to 3 on a relevance scale). The “onion” also includes domains that are mandatory in specific circumstances (i.e., disease-specific core set), other optional domains (i.e., important but not meeting criteria for mandatory domains), and domains requiring more research that were not voted upon.

The working group then developed: (a) a one-page summary of the core domain set; (b) an evidence summary with justification for including each domain; (c) a video of the plenary session to explain the steps taken, and modifications made to the core set; and (d) online discussion boards to elicit feedback from individuals who intended to attend the virtual workshops.

### *Conducting virtual workshops*

The workshop was originally designed to include both virtual and face-to-face participants. Due to the COVID-19 pandemic, the in-person meeting was canceled, and an alternative process was developed. Two pilot virtual workshops were conducted with a few participants to test the feasibility of the virtual format (May 2020). This was followed by two final virtual workshops with broader participation (July 2020). Participants at the pilot and final virtual workshops included OMERACT members and survey participants. Participants were asked to register online, and two separate times were scheduled for each workshop to enable participation across different time zones.

A few weeks before the virtual workshops, participants were asked to complete general OMERACT training prepared by the OMERACT executives (i.e., videos and training modules) to clarify the OMERACT process. Participants were also asked to view two white-board videos on SDM and the video of our plenary session. Pre-workshop material (White Paper, one-page summary, evidence summary) was available on the OMERACT website and mobile application. Participants were encouraged to post comments and questions on the discussion boards.

At the virtual workshops, participants were reminded of the goal of the core domain set and were divided into breakout groups of 8–15 participants to discuss any questions and comments they had, and to resolve any disagreement. Workshops lasted 90 min, with approximately 30 min used for breakout groups. OMERACT trained-facilitators moderated breakout group discussions, while reporters took notes and content experts answered questions in each breakout group. After the breakout groups, reporters summarized each group's discussions to the larger group. Finally, participants were asked to formally endorse the core domain set. To be endorsed, at least 70% of participants in both stakeholder groups needed to agree that the domains were mandatory. An anonymous vote was conducted for the entire core domain set via the OMERACT mobile application. If fewer than 70% of participants endorsed it, another vote was to be conducted for each domain separately.

## **Results**

### *Draft core domain set*

Based on discussions among the working group, we made minor revisions to previously proposed domains [13], and added a domain deemed mandatory by OMERACT that represents potential harms of SDM interventions. The resulting draft core domain set included six domains: 1- Knowledge of all options, their potential benefits and

risks; 2- Choice of an option aligned with each patient's values and preferences; 3- Confidence in the chosen option; 4- Satisfaction with the decision-making process; 5- Adherence to the chosen option and 6- Potential negative consequences (e.g., difficult to use, stressful, costly, time-consuming) (see Table 1 for definitions).

### *White-board videos*

The working group agreed that the videos should use a plain language, visually-engaging presentation that captures the core domains, and presents a clinical case. One video explained the SDM process (video 1) [19] and the other explained SDM outcomes and the draft core domain set (video 2) [20]. Videos were viewed about 200 times each on YouTube by the time the survey was conducted.

### *International survey*

A total of 167 individuals responded to the electronic survey (103 being patients/caregivers), and between 135 and 144 respondents answered each of the various questions (Table 2). Participants represented 28 countries and four continents (North America, Europe, Australia, Asia). The majority of participants were female, and about half consisted of patients/caregivers. About half of respondents had no experience with SDM, while half had either participated in SDM studies or developed SDM interventions. A total of 142 respondents (85%) reported they watched both SDM videos and 3 respondents (2%) watched only the first video.

Overall, respondents from both stakeholder groups rated all domains as *relevant* and *clear* (Table 3). The proportion of respondents who rated the various domains as being *relevant* ranged from 81% to 95%. The proportion of respondents who rated the various domains as being *clear* ranged from 82% to 93%. Proportions were slightly different between stakeholder groups for some domains, with “Satisfaction with the decision-making process” and “Adherence to the chosen option” being more relevant for patients/caregivers and “Confidence in the chosen option” being more relevant for clinicians/researchers. Some respondents suggested clarification of names and definitions of domains (see Table 1).

### *Final proposed core domain set, evidence summaries and online discussion boards*

Informed by the survey, the working group clarified the domains and their definitions (see Table 1). The final core domain set was presented in the OMERACT “onion” (see Fig. 1) with six domains deemed mandatory and three prospective domains requiring further evidence [12,13]. No optional domains were suggested for inclusion.

Pre-conference material and links to white-board videos and discussion boards were posted on the OMERACT website [21]. A total of 128 individuals registered as members of the online discussion boards and posted questions focused mostly on when to use the core domain set, what domains meant and how adherence to treatment is a more distal outcome compared to the others.

### *Virtual workshops*

A total of 149 individuals participated in the two pilot ( $n = 32$ ) and two main workshops ( $n = 117$ ). Since there were no differences in format and results, all workshops' results are reported together. A total of 48 patients/caregivers and 101 clinicians/scientists participated. When asked which material they had reviewed prior to the workshops, 96% of participants reported watching the white-board videos, while 88% reported reading the pre-conference material, watching the plenary session video and participating in the online discussion boards. Most participants (95%) were confident in their knowledge based on reviewing the material. The core domain set

**Table 1**  
Domains and their definitions before and after the electronic survey, along with comments from survey participants.

Domains before the survey	Comments from survey participants	Domains after the survey (proposed for final vote at the workshops)
<p><b>Knowledge of all options, their potential benefits and risks</b></p> <p>Description: The shared decision making intervention helps patients understand the available options and their potential benefits, as well as <b>risks</b>. It also helps them to know the <b>probabilities</b> (chances) of benefits and <b>risks in an accurate manner</b>.</p> <p><b>Choice of an option</b> aligned with each patient's values and preferences</p> <p>Description: The shared decision making intervention helps patients choose the treatment option that matches their values and preferences. It means they chose the treatment option that has the features that they value most.</p>	<p>- it was not realistic or feasible to give "all" the options</p> <p>- preferred the word "harms" which is used more commonly in trials</p> <p>- described the word "probabilities" as confusing</p> <p>- preferred lay-language terms</p> <p>- the last part of the sentence was redundant</p> <p>- wording lacked clarity</p> <p>- asked for examples of the "features" of treatment options</p>	<p><b>Knowledge of options, their potential benefits and harms</b></p> <p>Description: The shared decision making intervention helps patients understand the options and their potential benefits and <b>harms</b>. It also helps them understand the <b>chances</b> of benefits and <b>harms</b>.</p> <p><b>Chosen option</b> aligned with each patient's values/ preferences</p> <p>Description: The shared decision making intervention helps patients choose the treatment option that matches their values and preferences. It means they chose the treatment option that has the features (<b>benefits, harms and practical aspects</b>) that they value most.</p>
<p><b>Confidence in the chosen option</b></p> <p>Description: The shared decision making intervention helps patients feel sure they made the best decision. It means they feel confident in the decision they made.</p>	<p>- should explain that best decision depends on what matters to each individual</p>	<p><b>Confidence in the chosen option</b></p> <p>Description: The shared decision making intervention helps patients feel sure they made the best decision <b>for themselves</b>. It means they feel confident in the decision they made.</p>
<p><b>Satisfaction with the decision-making process</b></p> <p>Description: The shared decision making intervention helps patients feel satisfied about the way they made the decision and about their level of involvement.</p>	<p>No comments</p>	<p>No change</p>
<p><b>Adherence to the chosen option</b></p> <p>Description: The shared decision making intervention helps patients follow through with the chosen treatment option. It means they start using the option they chose.</p>	<p>- described adherence as beyond starting to use a treatment option to include continuing as well.</p>	<p><b>Adherence to the chosen option</b></p> <p>Description: The shared decision making intervention helps patients follow through with the chosen treatment option. It means they start <b>and continue</b> using the option they chose.</p>
<p><b>Potential negative consequences (e.g., difficult to use, stressful, costly, time-consuming)</b></p> <p>Description: The shared decision making intervention may have potential negative consequences, such as being difficult to use, stressful, or take too much time or money.</p>	<p>- concern that "potential negative consequences" pertained to treatment options and not to the SDM intervention.</p>	<p><b>Potential negative consequences of the SDM intervention</b></p> <p>Description: The shared decision making intervention may have potential negative consequences, such as being difficult to use, stressful, or take too much time or money.</p>

Changes between the two core domain sets are highlighted in bold.

**Table 2**  
Characteristics of participants in the electronic survey.

Types of characteristics	Participants (%) (n = 167)
<b>Sex</b>	
Female	82
<b>Experience in SDM</b>	
No experience in SDM	53
Limited (i.e., participated in a shared decision making intervention study)	27
Experienced (i.e., developed shared decision making interventions)	20
<b>Role*</b>	
Patient	63
Clinician	36
Researcher	22
Caregiver (e.g., family member of individual with arthritis)	4
Member of Industry	2
Policy Maker	1
Other (e.g., consumer advocates, patient partners, research students)	5
<b>Geographic location</b>	
Canada	30
United States of America	15
United Kingdom	12
The Netherlands	8
Other European Countries	24
Australia/New Zealand	9
Asia	2
Other	1

n: number of participants.

\* Some respondents had more than one role.

obtained an overall endorsement of 95%, with 99% endorsement by patients/caregivers and 93% endorsement by clinicians/scientists. The definitions of the final domains are shown in Table 4.

## Discussion

An international group of individuals that included patients, clinicians and researchers achieved consensus on the OMERACT core domain set for SDM interventions in rheumatology trials. This core domain set is unique and focuses on outcomes of SDM interventions, both benefits and harms. The core domain set highlights the importance of domains such as knowledge of the options, and alignment between patients' chosen option and their values/preferences. These are closely linked to the outcome that was recommended by another research group to assess effectiveness of patient decision aids (i.e., improved match between chosen option and features that matter most to the informed patient) [10]. In addition, the core set acknowledges patients' experiences with a specific SDM intervention in terms of their confidence in their chosen option, their satisfaction with the process, and whether they used the chosen option. Finally, the core set assesses potential negative consequences of the SDM intervention to assess safety. Assessing these domains can determine the advantages of a given SDM intervention, but also the pitfalls which could lead to improved SDM endeavours in the future. Future work will identify outcome measures for the domains.

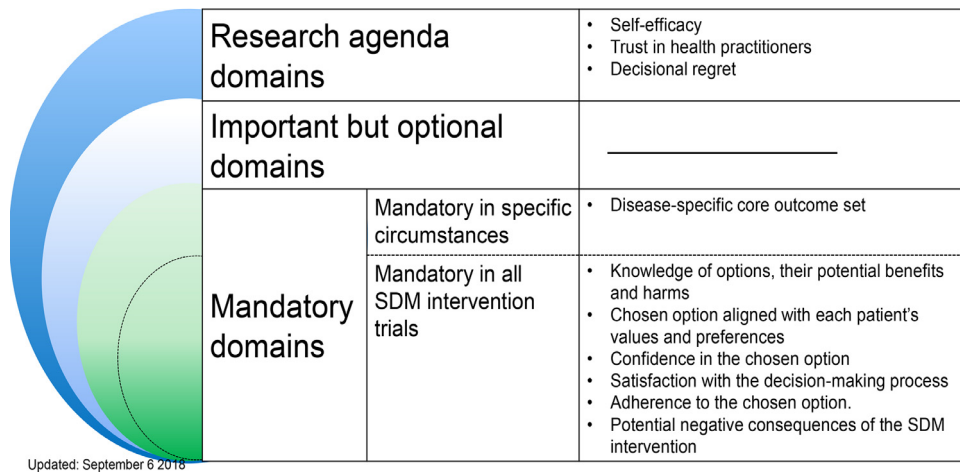
Our work showed that strategies that were co-developed with PRPs, such as white-board videos, summaries and discussion boards, helped promote understanding of a complex and unconventional

**Table 3**  
Relevance and clarity of each domain according to respondents of the electronic survey.

Domains	Question	Results (%*)		
		Patients/Caregivers** (n = 87)	Clinicians/Researchers and others (n = 57)	Total (n = 144)
Knowledge of options	Relevance	93	96	94
	Clarity	92	93	92
Choice of an option aligned with each patient's values and preferences	Relevance	96	93	95
	Clarity	90	89	90
Confidence in the chosen option	Relevance	88***	95	91
	Clarity	88	91	89
Satisfaction with the decision-making process	Relevance	96***	84	92
	Clarity	95***	89	93
Adherence to the chosen option	Relevance	93***	86	91
	Clarity	89***	82	86
Potential negative consequences	Relevance	81***	80	81
	Clarity	84***	77	82

\* The number and percentage of participants who rated a level of relevance and clarity of 7 or higher on a scale of 1 to 9.  
 \*\* Respondents who identified as a patient or caregiver were categorized as such even they also identified as a clinician or other role.  
 \*\*\* These values have between 5% and 10% of missing data.

### The OMERACT Onion: Organization of domains Working Group: Shared Decision Making



**Fig. 1.** Final OMERACT SDM Core Domain Set.

**Table 4**  
Final OMERACT core domains and definitions.

Domains and Definitions
<p><b>Knowledge of options, their potential benefits and harms</b> The shared decision making intervention helps patients understand the options and their potential benefits and harms. It also helps them understand the chances of benefits and harms.</p> <p><b>Chosen option aligned with each patient's values/preferences</b> The shared decision making intervention helps patients choose the treatment option that matches their values and preferences. It means they chose the treatment option that has the features (benefits, harms and practical aspects) that they value most.</p> <p><b>Confidence in the chosen option</b> The shared decision making intervention helps patients feel sure they made the best decision for themselves. It means they feel confident in the decision they made.</p> <p><b>Satisfaction with the decision-making process</b> The shared decision making intervention helps patients feel satisfied about the way they made the decision and about their level of involvement.</p> <p><b>Adherence to the chosen option</b> The shared decision making intervention helps patients follow through with the chosen treatment option. It means they start and continue using the option they chose.</p> <p><b>Potential negative consequences of the SDM intervention</b> The shared decision making intervention may have potential negative consequences, such as being difficult to use, stressful, or take too much time or money.</p>

new core domain set. Prior to using these strategies, we had faced challenges in communicating our domains as reflected by the lack of endorsement at OMERACT 2016. In contrast, our current approach led to a strong endorsement of the core domain set by participants at the virtual workshops, and a high level of confidence in their knowledge.

Our approach actively engaged key stakeholders within our working group, including PRPs, who were involved not only as participants, but as leaders, thus helping to foster meaningful patient engagement [22]. This approach, combined with innovative consensus-building strategies, possibly helped engage participants from key stakeholder groups, indicated by the high level of participation, and the high proportion of participants who viewed the videos and read the material. This is especially true for patients/caregivers whose representation at the virtual workshop was four times higher in 2020 compared to 2016 (32% of 149 participants in 2020 vs. 8% of 96 participants in 2016). Findings provide further justification for OMERACT groups to use innovative strategies such as white-board videos for consensus-building, as suggested by the OMERACT Filter 2.1 [15].

*Limitations*

Despite concerted efforts to engage patients and caregivers throughout the process, some populations were likely not reached,

such as patients/caregivers from across all sociodemographic and language groups, or those with technology barriers or lack of Internet access. Future work will address these shortcomings.

## Conclusion

The use of virtual consensus-building methods following the OMERACT Filter 2.1 methodology, grounded in a patient-oriented approach, led to strong endorsement of a core domain set for SDM interventions in rheumatology trials. This approach succeeded in engaging key stakeholders throughout each step and helped refine, clarify and ensure proper understanding of this complex and unconventional core domain set. The core domain set showed strong endorsement by key stakeholders, including patients/caregivers, who were an integral part of this work. Future research will include the development of a core outcome measurement set to identify instruments to assess these domains in trials of SDM interventions.

## Declaration of Competing Interest

Karine Toupin-April, Simon Décary, Maarten de Wit, Alexa Meara, Jennifer L. Barton, Liana Fraenkel, Linda C. Li, Peter Brooks, Beverley Shea, Dawn Stacey, France Légaré, Anne Lyddiatt, Cathie Hofstetter, Laurie Proulx, Marieke Voshhaar, Maria E. Suarez-Almazor, Tanya Meade, Janet Elizabeth Jull, Willemina Campbell, Rieke Alten, Esi M. Morgan, Ayano Kelly, Jessica Kaufman, Lara J. Maxwell, Francis Guillemin, Dorcas Beaton, Yasser El-Miedany, Shikha Mittoo, Tiffany Westrich Robertson, Susan J. Bartlett, Melissa Mannion, Samah Ismail Nasef, Savia de Souza, Anne Boel, Adewale Adebajo, Laurent Arnaud, Tiffany Gill, Ellen Moholt, Jennifer Burt, Aruni Jayatileke, Ihsane Hmamouchi, David Carrott, Kate Mather, Ajesh Maharaj, Saurab Sharma, Francesco Caso, Christopher Fong, Allyson Jones, Regina Greer-Smith, Akpabio Akpabio, Valerie Umaefulam, Sara Monti, Charmaine Melburn, Kirsten Schultz, Simon Stones, Sonam Kiwalkar, Hemalatha Srinivasalu, Deb Constien, Lauren K. King and Peter Tugwell have nothing to disclose.

Robin Christensen reports other from Lecture: Research Methods (Pfizer, DK; 2017), other from Lecture: GRADE Lecture (Celgene, DK; 2017), other from Ad Board Lecture: CAM (Orkla Health, DK; 2017), other from Project Grant: "GreenWhistle" (Mundipharma, 2019), other from Lecture: Diet in RMD (Novartis, DK; 2019), other from Consultancy Report: Network MA's (Biogen, DK; 2017), other from Ad Board Lecture: GRADE (Lilly, DK; 2017), other from Consultancy Report: GRADE (Celgene, 2018), other from Lecture: Network MA's (LEO; 2020), outside the submitted work; and Musculoskeletal Statistics Unit, The Parker Institute is grateful for the financial support received from public and private foundations, companies and private individuals over the years. The Parker Institute is supported by a core grant from the Oak Foundation; The Oak Foundation is a group of philanthropic organizations that, since its establishment in 1983, has given grants to not-for-profit organizations around the world.

Annelies Boonen reports grants from Abbvie, grants from Celgene, other from UCB, other from Galapagos, other from Eli Lilly, outside the submitted work.

Lyn March reports personal fees from Pfizer Australia, personal fees from Abbvie Australia, grants from Janssen Australia, outside the submitted work; Dr March is a member of OMERACT executive that receives arms-length funding from 9 companies.

Willemina Campbell received OMERACT funded travel to a conference to attend meetings in regard to this paper.

Sophie Hill is the Coordinating Editor of the Cochrane Consumers and Communication Group which publishes reviews of the evidence on shared decision making.

Jasvinder Singh reports personal fees from Crealta/Horizon, Medisys, Fidia, UBM LLC, Trio health, Medscape, WebMD, Adept Field Solutions, Clinical Care options, Clearview healthcare partners,

Putnam associates, Focus forward, Navigant consulting, Spherix, Practice Point communications, the National Institutes of Health and the American College of Rheumatology, personal fees from Simply Speaking, other from Vaxart pharmaceuticals and Charlotte's Web Holdings (current); Amarin, Viking, and Moderna (previously owned), non-financial support from FDA Arthritis Advisory Committee, non-financial support from Steering committee of OMERACT, an international organization that develops measures for clinical trials and receives arms' length funding from 12 pharmaceutical companies, non-financial support from Veterans Affairs Rheumatology Field Advisory Committee, non-financial support from Editor and the Director of the UAB Cochrane Musculoskeletal Group Satellite Center on Network Meta-analysis, outside the submitted work.

Francisco J. Blanco reports grants from Abbvie, grants and personal fees from Pfizer, grants from UCB, grants from Bristol-Mayers Squibb, grants from Roche, grants from Servier, grants from Bioiberica, grants from Sanofie, grants from Grunenthal, grants from GlaxoSmithKline, grants from Lilly, grants from Janssen, grants from Regeneron, grants from Amgen, grants from TRB Chemedica, outside the submitted work.

Anthony P. Fernandez reports personal fees and other from AbbVie, grants, personal fees and other from Novartis, grants, personal fees and other from Mallinkrodt, other from Corbus, other from Pfizer, outside the submitted work.

Sarah Mackie reports other from Roche Chugai, non-financial support from Roche, other from Sanofi, outside the submitted work; and Patron of the patient charity PMRGCAuk.

Elena Nikiphorou reports personal fees and other from AbbVie, personal fees and other from Eli-Lilly, personal fees and other from Gilead, personal fees and other from Celltrion, personal fees and other from Pfizer, other from Sanofi, outside the submitted work.

Victor S. Sloan reports having served as paid consultant to various pharmaceutical companies and healthcare consultancies providing advice on clinical research and advisory committee preparation outside the scope of the submitted work. Shareholder in UCB Pharma.

Vibeke Strand reports consulting fees from AbbVie, Amgen, Arena, AstraZeneca, BMS, Boehringer Ingelheim, Celltrion, CORRONA, Crescendo/Myriad, Equillium, Genentech/Roche, GSK, Horizon, Inmedix, Janssen, Eli Lilly, Novartis, Pfizer, Regeneron Pharmaceuticals Inc., Samsung, Sandoz, Sanofi, TwoXAR and UCB, outside the submitted work.

## Acknowledgments

The authors would like to thank Shawna Grosskleg, Laure Gossec, Sarah Collins, Thomas Chong, Pamela Richards, Ailsa Bosworth, Pamela Montie, Jennifer Petkovic, Vicki Evans, Cécile Gaujoux-Viala, Anne Stiggelbout, Suvi Karuranga, Ian M. Disend and Andrea Boyd. We would like to thank the Canadian Arthritis Patient Alliance (CAPA), the EULAR PARE (People with Arthritis and Rheumatism) network and EULAR PRPs, GRAPPA (Group for Research of Psoriasis and Psoriatic Arthritis) PRPs, the International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis), Creaky Joints, Joint Health, SAVVY Coop, S.T.A.R Initiative, the Childhood Arthritis and Rheumatology Research Alliance (CARRA), the Cochrane Musculoskeletal consumer group, Versus Arthritis UK, Arthritis Care Netherlands, Vasculitis UK, Osteoarthritis Research Society International (OARSI), Dragon Claw and the Canadian Rheumatology Association.

## Funding

Funding for travel awards to the OMERACT conference were provided by OMERACT. This funding was reported to OMERACT 2022 because of the Covid-19 pandemic. K. Toupin-April is funded by The Arthritis Society, the Chronic Pain Network (a Network funded by the Canadian Institutes of Health Research (CIHR) Strategy for Patient

Oriented Research (SPOR), the Ontario Ministry of Economic Development, Job Creation and Trade and the Children's Hospital of Eastern Ontario Research Institute. S. Décaré received a Banting postdoctoral salary award from Canadian Institutes for Health Research. J. L. Barton's research reported in this publication was supported by the National Institute of Arthritis and Musculoskeletal and Skin Diseases, part of the National Institutes of Health, under Award Number [K23AR-064372](#). L. Fraenkel's research reported in this publication was supported by the National Institute of Arthritis and Musculoskeletal and Skin Diseases, part of the National Institutes of Health, under Award Number [AR060231-01](#). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. L. C. Li holds the Harold Robinson/Arthritis Society Chair in Arthritic Diseases, and is supported by the Canada Research Chair Program. D. Stacey holds a University of Ottawa Research Chair in Knowledge Translation to Patients. F. Légaré holds a Tier 1 Canada Research Chair in Shared Decision Making and Knowledge Translation. R. Christensen's research at the Parker Institute is supported by grants from The Oak Foundation ([OCAY-13-309](#)). L. March's research is supported by the Northern Sydney Local Health District. S. Hill is supported by La Trobe University. P. Tugwell holds a Canada Research Chair.

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