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Consensus on the definitions and descriptions of the domains of the OMERACT Core Outcome Set for shared decision making interventions in rheumatology trials

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Abbreviations: OMERACT, Outcome Measures in Rheumatology; SDM, shared decision making; PRPs, patient research partners; WG, working group.

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ABSTRACT

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

Methods: Following the OMERACT Handbook methods, our Working Group (WG), comprised of 90 members, including 17 patient research partners (PRPs) and 73 clinicians and researchers, had six virtual meetings in addition to email exchanges to develop draft definitions and descriptions. The WG then conducted an international survey of its members to gain consensus on the definitions and descriptions. Finally, the WG members had

virtual meetings and e-mail exchanges to review survey results and finalize names, definitions and descriptions of the domains.

Results: WG members contributed to developing the definitions. Fifty-two members representing four continents and 13 countries completed the survey, including 15 PRPs, 33 clinicians and 37 researchers. PRPs and clinicians/researchers agreed with all definitions and descriptions with agreements ranging from 87% to 100%. Respondents suggested wording changes to the names, definitions and descriptions to better reflect the domains. Discussions led to further simplification and clarification to address common questions/concerns about the domains.

Conclusion: Our WG reached consensus on the definitions and descriptions of the domains of the core domain set for rheumatology trials of SDM interventions. This step is crucial to understand each domain and provides the foundation to identify instruments to measure each domain for inclusion in the Core Outcome Measurement Set.

Clinical significance: The current study provides consensus-based definitions and descriptions for the domains of the OMERACT core domain set for shared decision making interventions from patients/caregivers, clinicians and researchers. This is a crucial step to understand each domain and provides the foundation to identify instruments to measure each domain for inclusion in the Core Outcome Measurement Set for trials of SDM interventions.

Introduction

Shared decision making (SDM) is an imperative to ensure optimal care in rheumatology [1–2]. Since SDM is not consistently used in practice, various interventions have been developed and evaluated to facilitate SDM, such as patient decision aids, decision coaching and health care provider training [3–5]. Outcome measures in trials of SDM interventions lack standardization [3–5] limiting the ability to compare study results. To ensure that research conducted over time can be combined to understand the effectiveness of these interventions, a set of the most relevant outcome domains is needed to inform outcome measure selection for future clinical trials.

The goal of the Outcome Measures in Rheumatology (OMERACT) SDM Working Group (WG) is to gain consensus on a Core Outcome Set for trials of SDM interventions (<https://omeract.org/working-groups/sdm/>). The OMERACT SDM WG is classified as a ‘bolt-on’ group. ‘Bolt-on groups’ describe the additional domains and instruments that are part of a specific intervention, and which are measured in addition to disease-specific core outcome sets. In a clinical trial of SDM interventions, the trial must measure both the core outcome set specific to the concept of SDM and include the disease-specific core outcome set of the clinical trial’s study population. By doing so, we ensure that we measure both intervention-specific and disease-specific outcomes.

In 2021, OMERACT endorsed the Core Domain Set of outcomes for rheumatology trials of SDM interventions [6]. This Core Domain Set includes six outcome domains of the SDM process which should be evaluated in trials evaluating the effectiveness and safety of SDM interventions in rheumatology: 1) Knowledge of options; 2) Alignment of chosen option with values; 3) Confidence in the chosen option; 4) Satisfaction with the decision-making process; 5) Adherence to the chosen option; 6) Potential negative consequences (of the SDM intervention) [6]. Initial definitions were developed for each domain based on previous qualitative work and calls with the OMERACT SDM WG.

Recent guidance from OMERACT includes the development and agreement on the definitions and in-depth descriptions of domains to ensure each domain is thoroughly defined and to help inform the search to find instruments that match the domains for inclusion in the Core Outcome Measurement Set [7]. Thus, our group used consensus-building activities with patient research partners (PRPs) with a rheumatic or musculoskeletal disease, clinicians and researchers to develop detailed descriptions and gain consensus on definitions and detailed descriptions of the domains.

Material and methods

Study design

Following the OMERACT Handbook methods [8] and OMERACT recommendations for PRP involvement [9], the WG used a 3-step

consensus-building process with active involvement from PRPs, clinicians and researchers. First, we held virtual WG meetings to develop the definitions and descriptions of the domains of the core domain set. Second, the WG conducted an online survey to gain consensus on the domain definitions and descriptions. Finally, we discussed findings with the team via virtual meetings and e-mail exchanges and agreed on modifications to the domains. The project was approved by the Children’s Hospital of Eastern Ontario Research Ethics Board, Canada (REB#16/07X).

Steps

Discussions among working group members

The WG met over six one-hour virtual meetings from November to December 2022 to develop definitions and descriptions of each domain. In parallel, WG chairs sent documents to the group and asked for verbal and/or written feedback. The WG currently includes 90 members, comprised of 17 PRPs, and 73 clinicians, researchers, policy makers and members of the industry from four continents and 15 countries. Members’ levels of expertise in SDM ranged from novice to expert.

Conducting an online survey

The survey was written in English lay language using feedback from the OMERACT SDM WG, including a panel of PRPs. The survey questionnaire included two parts: (1) questions about agreement with each definition and detailed description (and their components for complex domains); (2) open-ended questions asking for suggested changes to definitions and descriptions.

In December 2022, the survey was distributed via e-mail to members of the OMERACT SDM WG. We sought responses from different groups (i.e., PRPs/caregivers, clinicians, researchers and others) from various continents. Participants provided consent before completing the survey. The survey was expected to take about 10 minutes to complete via REDCap. We sent three reminders over the course of a month.

For each domain, we summarized the number of respondents and the percentage of individuals who agreed with the definitions/descriptions across all stakeholder groups and separately for each group (PRPs/caregivers vs. clinicians/researchers/other). We also summarized suggestions to improve the definitions and detailed descriptions. We set the threshold for consensus to 70%, in line with previous OMERACT surveys [10]. Had this threshold not been reached, a second round would have been completed after making modifications.

Discussions among working group members

A co-chair of the WG summarized the results and respondents’ comments to the survey, and WG members discussed these on six one-hour virtual meetings from January to April 2023 to agree on changes to finalize definitions and descriptions.

Table 1
Domains and their definitions and descriptions before and after the survey and team discussions.

Initial domain names, definitions and descriptions (before the survey)	Comments from survey participants and WG members	Finalized domain names, definitions and descriptions (after the survey and WG discussions)*
<p>DOMAIN 1: Knowledge of options, their potential benefits and harms</p> <p>Definition: Study participant's knowledge of the healthcare options and their potential benefits and harms, along with the chances (e.g., probabilities) of benefits and harms.</p> <p>Description: This domain includes two components:</p> <p>Component 1.1: -The study participant's knowledge of the options, their potential benefits and harms, and if appropriate and available, how likely they may happen (e.g., probabilities). Is the participant able to answer correctly questions on the options, benefits and harms?</p> <p>Component 1.2: -The study participant's feeling of being informed about the options, their potential benefits and harms, and if appropriate and available, how likely they may happen (e.g., probabilities). Does the participant feel informed about the options, benefits and harms?</p>	<p>Changes to the domain name: No change</p> <p>Changes to the definition: -Changed wording and made two sentences. -Added a mention of both components of the description -Added a mention "if probabilities are available"</p> <p>Changes to the description: Component 1.1: -Removed the notion of whether it is "appropriate" -Added a mention "if probabilities are available" Component 1.2: -Removed "and if appropriate and available, how likely they may happen (e.g., probabilities)."</p>	<p>DOMAIN 1: Knowledge of options, their potential benefits and harms</p> <p>Definition: <i>The study participant is knowledgeable and has a perception of being informed</i> about the options. <i>If probabilities are available, the study participant is knowledgeable about how likely the benefits and harms are to happen.</i></p> <p>Description: This domain includes two components:</p> <p>Component 1.1: -The study participant's knowledge of the options, their potential benefits and harms, and <i>if probabilities are available</i>, how likely they are to happen. Is the study participant able to correctly answer questions on the options, benefits and harms?</p> <p>Component 1.2: -The study participant's feeling of being informed about the options, their potential benefits and harms. Does the study participant feel informed about the options, benefits and harms?</p>
<p>DOMAIN 2: Chosen option aligned with each study participant's values/preferences</p> <p>Definition: The study participant's chosen treatment option matches with the study participant's values and preferences. It means the study participant chooses the treatment option that best matches the features (e.g., benefits, harms) that they value most.</p> <p>Description: This domain includes three components (voted together in the survey):</p> <p>Component 2.1: -The chosen option(s) after using the SDM intervention (A).</p> <p>Component 2.2: -The study participant's values* and preferences** when making that choice (B).</p> <p>Component 2.3: -The extent to which there is a concordance between (A) and (B).</p> <p><i>*In this context, values represent how the study participant rates each of the features (e.g., benefits, harms) of the health care options.</i> <i>**Preferences represent the study participant's preferences in terms of treatments.</i></p>	<p>Changes to the domain name: Changed wording</p> <p>Changes to the definition: -Removed the term "preferences" -Added a description of the chosen option with a * -Added the mode of administration and timing when defining values in the **</p> <p>Changes to the description: Component 2.2: -Removed the term "preferences" and simplified the explanation</p>	<p>DOMAIN 2: Chosen option aligned with <i>the</i> study participant's values</p> <p>Definition: The study participant's chosen option* matches with the study participant's values**. The study participant chooses the option that best matches the features (e.g., benefits, harms, mode of administration, timing) that they value most.</p> <p>Description: This domain includes three components:</p> <p>Component 2.1: -The chosen option(s)* after using the SDM intervention (A).</p> <p>Component 2.2: -The study participant's values** (B).</p> <p>Component 2.3: -The extent to which there is a concordance between (A) and (B).</p> <p><i>* The chosen option means any option that the participant chose when using the SDM intervention. It can include a wide variety of healthcare options.</i> <i>**In this context, values represent how the study participant rates each of the features (e.g., benefits, harms, mode of administration, timing) of the healthcare options.</i></p>
<p>DOMAIN 3: Confidence in the chosen option</p> <p>Definition: The study participant feels confident in the decision they made. It means they feel sure they made the best decision for themselves.</p> <p>Description: This domain includes one component: The study participant's perceived confidence in the chosen option. How confident is the study participant about the options they chose?</p>	<p>Changes to the domain name: Used the word "certainty" instead of "confidence"</p> <p>Changes to the definition: -Changed wording and used the words "sure or certain" instead of "confident"</p> <p>Changes to the description: -Changed wording and used the word "certainty" and "sure" instead of "confidence" and "confident"</p>	<p>DOMAIN 3: <i>Certainty</i> in the chosen option</p> <p>Definition: The study participant feels <i>sure or certain of the chosen option</i>. They feel sure they made the best decision for themselves.</p> <p>Description: This domain includes one component: The study participant's perceived certainty in the chosen option. How <i>sure</i> is the study participant <i>that they chose the best option for themselves</i>?</p>
<p>DOMAIN 4: Satisfaction with the decision-making process</p> <p>Definition: The study participant feels satisfied about the way they made the decision and about their level of engagement.</p> <p>Description: Component 4.1: -The extent to which the study participant feels satisfied about the way they made the decision (i.e., all the steps in the decision-making process such as identifying the decision, exchanging information, clarifying values/preferences, deliberating, making a decision).</p> <p>Component 4.2: -The extent to which the study participant feels satisfied about their level of engagement in the decision-making process, meaning how engaged they were.</p>	<p>Changes to the domain name: No change</p> <p>Changes to the definition: -Added clarification</p> <p>Changes to the description: Component 4.1: -Changed wording and added clarifications on the decision-making process Component 4.2: -Changed wording and added clarifications on the engagement in decision-making</p>	<p>DOMAIN 4: Satisfaction with the decision-making process</p> <p>Definition: The study participant feels satisfied about the way they made the decision and about their level of engagement <i>in the decision-making process</i>.</p> <p>Description: Component 4.1: -The extent to which the study participant feels satisfied about the way they made the decision (e.g., identifying the decision, exchanging information, clarifying values, deliberating, feeling prepared to make a decision).</p> <p>Component 4.2: -The extent to which the study participant feels satisfied about their level of engagement in the decision-making process, meaning how <i>involved</i> they were (e.g., <i>feeling heard, talked about what was important to them, asked questions to better understand the options</i>).</p>

(continued on next page)

Table 1 (continued)

Initial domain names, definitions and descriptions (before the survey)	Comments from survey participants and WG members	Finalized domain names, definitions and descriptions (after the survey and WG discussions)*
<p>DOMAIN 5: Adherence to the chosen option</p> <p>Definition: The study participant follows through with the chosen option.</p> <p>Description:</p> <p>Component 5.1: -The study participant starts using the option they chose (initiation phase)</p> <p>Component 5.2: -The study participant uses the option in the manner that was agreed upon with their health care providers (timing, frequency, dosing) (implementation phase)</p> <p>Component 5.3: -The study participant continues using the option they chose for the intended duration, if applicable (persistence phase)</p> <p>Component 5.4: -Reasons for non-adherence (there are many factors which may have an impact on adherence, other than the SDM intervention, and which have to be taken into account (e.g., occurrence of side effects)</p>	<p>Changes to the domain name: No change</p> <p>Changes to the definition: No change</p> <p>Changes to the description:</p> <p>Components 5.1-5.3: -Modified the description of adherence based on the type of options (i.e., options that patients follow over time (Components 5.1-5.3) vs. One-time procedures or tests (Component 5.4)) (see A and B)</p> <p>-Changed wording</p> <p>Component 5.4: -Changed wording and added potential reasons for non-adherence</p>	<p>DOMAIN 5: Adherence to the chosen option</p> <p>Definition: The study participant follows through with the chosen option.</p> <p>Description:</p> <p>A. Adherence for options that patients follow over time (e.g., medication, exercise routine):</p> <p>Component 5.1: The study participant starts using the chosen option (initiation phase)</p> <p>Component 5.2: The study participant uses the chosen option in the manner that was agreed upon (timing, frequency, dosing) with their <i>clinicians</i> (implementation phase)</p> <p>Component 5.3: The study participant continues using the chosen option for the intended duration, if applicable (persistence phase) or</p> <p>B. Adherence for one-time procedures or tests (e.g., surgery, injection, diagnostic test):</p> <p>Component 5.4: Proceed to have the procedure/test</p> <p>Component 5.5: -Reasons for non-adherence Many factors <i>may impact whether study participants use the chosen option, and should be taken into account if there is a concern for non-adherence</i> (e.g., occurrence of side effects, costs, limited health literacy)</p> <p>DOMAIN 6: Potential negative consequences of the SDM intervention</p> <p>Definition: Potential negative consequences that may arise from using the SDM intervention, such as being difficult to use, stressful, or requiring too much time or money.</p> <p>Description:</p> <p>In life impact:</p> <p>Component 6.1: -Difficulty for the study participant to use the SDM intervention</p> <p>Component 6.2: -The study participant's perceived stress related to the use of the SDM intervention</p> <p>In resource use:</p> <p>Component 6.3: -Time to use the SDM intervention</p> <p>Component 6.4: -Cost of using the SDM intervention (cost of using it and cost stemming from the use of the chosen options)</p>
<p>DOMAIN 6: Potential negative consequences of the SDM intervention</p> <p>Definition: Potential negative consequences that may arise from using the SDM intervention, such as being difficult to use, stressful, or requiring too much time or money.</p> <p>Description:</p> <p>In life impact:</p> <p>Component 6.1: -Difficulty for the study participant to use the SDM intervention</p> <p>Component 6.2: -The study participant's perceived stress related to the use of the SDM intervention</p> <p>In resource use:</p> <p>Component 6.3: -Time to use the SDM intervention</p> <p>Component 6.4: -Cost of using the SDM intervention (cost of using it and cost stemming from the use of the chosen options)</p>	<p>Changes to the domain name: No change</p> <p>Changes to the definition: No change</p> <p>Changes to the description:</p> <p>Component 6.1: -Added potential reasons for difficulty to use the SDM intervention</p> <p>Component 6.2: -Replaced "perceived stress" by "emotional distress"</p> <p>-Added "decision regret"</p> <p>Component 6.3: -Changed wording</p> <p>Component 6.4: -Changed wording</p> <p>-Added "physical space and technology required to use the SDM intervention"</p>	<p>DOMAIN 6: Potential negative consequences of the SDM intervention</p> <p>Definition: Potential negative consequences that may arise from using the SDM intervention, such as being difficult to use, stressful, or requiring too much time or money.</p> <p>Description:</p> <p>In life impact:</p> <p>Component 6.1: -Difficulty for the study participant to use the SDM intervention (e.g., requires high literacy to use, not available in participant's language, requires technical skills or technology)</p> <p>Component 6.2: -The study participant's perceived emotional distress related to the use of the SDM intervention or decision regret</p> <p>In resource use:</p> <p>Component 6.3: -Time required to use the SDM intervention</p> <p>Component 6.4: -Cost of using the SDM intervention (cost of using <i>the SDM intervention</i> and cost stemming from the use of the chosen options)</p> <p>-Physical space and technology required to use the SDM intervention</p>

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

Results

Definitions and descriptions

WG members contributed to developing the definitions and descriptions for each of the domains on virtual meetings as well as e-mail exchanges (Table 1 for the initial definitions and descriptions before the survey).

Survey

Fifty-two WG members (58% response rate) from four continents and 13 countries answered the survey, including 15 PRPs/caregivers, 33 clinicians and 37 researchers (Table 2 for respondents' characteristics). Some participants did not answer all questions (50 to 52 answered questions). Most respondents were women and had experience with SDM. PRPs/caregivers reported seven different rheumatic and

musculoskeletal diseases. Clinicians were mostly rheumatologists/physicians (55%) and a few were allied health providers (e.g., 6% physical therapists, 3% psychologists).

Respondents agreed with all definitions and descriptions with agreement ranging from 87% to 100% for PRPs/caregivers and 89% to 100% for clinicians/researchers (Table 3 for agreement levels). A few respondents suggested modifying and clarifying the definitions and descriptions to better reflect the domains. Some of the comments raised some questions/concerns about the use of certain terms such as probabilities, knowledge, values versus preferences, certainty versus confidence, engagement versus involvement, adherence, and non-adherence.

Finalized domains, definitions and descriptions

WG calls and e-mail exchanges led to additional changes to address common questions/concerns about the domains and finalize the name of the domains, their definitions and descriptions (Table 1 for the finalized

Table 2
Characteristics of participants in the electronic survey.

Types of characteristics	Participants (n=52) n (%)
Gender identity*	
Women	33 (65)
Men	17 (33)
Other	1 (2)
Experience in SDM**	
No experience in SDM	7 (14)
Limited (i.e., participated in a shared decision making intervention study)	18 (36)
Experienced (i.e., developed shared decision making interventions)	25 (50)
Role***	
Patient research partners	15 (29)
Clinicians	33 (64)
Rheumatologists	14
Other physicians	4
Nurses	3
Physical therapists	2
Occupational therapists	1
Psychologists	1
Researchers	37 (71)
Caregivers (e.g., family member of individual with arthritis)	2 (4)
Policy Makers	1 (2)
Geographic location	
Canada	15
United States of America	10
United Kingdom	3
Denmark	3
France	3
Other European Countries (The Netherlands, Germany, Norway, Spain, Italy)	6
Australia/New Zealand	7
Africa (Egypt, Morocco)	2
Reported diagnoses of patient research partners/Caregivers*	
Psoriatic arthritis	4
Rheumatoid arthritis	3
Osteoarthritis	3
Ankylosing spondylitis	2
Juvenile idiopathic arthritis	2
Osteoporosis	1
Chronic musculoskeletal pain	1

n: number of participants

* n=51

**n=50

***Some respondents had more than one role and more than one rheumatic condition. Some respondents also did not disclose the information.

names, definitions and descriptions and a summary of the changes made). The Target domain definition report summarizes the finalized definitions and descriptions (supplementary material).

For Domain 1 (knowledge), members expressed that if probabilities are available, study participants should be knowledgeable about how likely the benefits and harms are to happen. For Domain 2 (option aligns with values), participants suggested removing the term “preference” since it led to confusion. For Domain 3 (confidence in the chosen option), participants suggested replacing “confidence” with “certainty” to better reflect the construct of interest. For Domain 4 (satisfaction with decision-making process), only minor suggestions for clarification were received. For Domain 5 (adherence), participants mentioned that the description of adherence should vary based on the type of options (i.e., options that patients follow over time versus one-time procedures or tests). For Domain 6 (potential negative consequences), participants suggested replacing “perceived stress” with “emotional distress” and to add “decision regret”, as well as the physical space and technology needed to use the SDM intervention.

Discussion

Following the OMERACT Handbook and engaging PRPs throughout

Table 3
Agreement levels for each definition and description according to the survey.

Domains	Results (%)		
	Clinicians / Researchers/ others (n=37**)	Patient research partners / Caregivers* (n=15)	Total (n=52**)
	Agreement n (%)	Agreement n (%)	Agreement n (%)
1. Knowledge of options			
Definition	35 (97)	14 (93)	49 (96)
Detailed description			
Component 1.1	34 (92)	14 (93)	48 (92)
Component 1.2	34 (92)	15 (100)	49 (94)
2. Choice of an option aligned with each patient's values and preferences			
Definition	35 (100)	15 (100)	50 (100)
Detailed description	33 (94)	15 (100)	48 (96)
3. Confidence in the chosen option			
Definition	35 (100)	14 (93)	49 (98)
Detailed description	33 (94)	13 (87)	46 (92)
4. Satisfaction with the decision-making process			
Definition	35 (100)	15 (100)	50 (100)
Detailed description			
Component 4.1	35 (100)	15 (100)	50 (100)
Component 4.2	34 (97)	14 (93)	48 (96)
5. Adherence to the chosen option			
Definition	34 (97)	14 (93)	48 (96)
Detailed description			
Component 5.1	33 (94)	14 (93)	47 (94)
Component 5.2	34 (97)	14 (93)	48 (96)
Component 5.3	34 (97)	14 (93)	48 (96)
Component 5.4	31 (89)	14 (93)	45 (90)
6. Potential negative consequences			
Definition	32 (91)	15 (100)	47 (94)
Detailed description			
Component 6.1	35 (100)	15 (100)	50 (100)
Component 6.2	35 (100)	15 (100)	50 (100)
Component 6.3	35 (100)	15 (100)	50 (100)
Component 6.4	34 (97)	14 (93)	48 (96)

* Respondents who identified as a patient or caregiver were categorized as such even they also identified as a clinician or other role.

** Number of respondents to the survey. However, there were missing data for some of the domains.

the process, our WG reached consensus on the definitions and descriptions of the core domain set for rheumatology trials of SDM interventions. This international effort has engaged individuals from many countries and various groups with a range of expertise in SDM. Participating PRPs have a variety of rheumatic and musculoskeletal diseases and clinicians represent various professions.

The current work was crucial since it identified refinements to make to the domain names, definitions and descriptions and led to consensus. Having team discussions in various formats (synchronous and asynchronous) over time helped to ensure that all voices were heard. Engaging PRPs, clinicians and researchers in a meaningful manner helped achieve our goal and ensures that our domains and descriptions are clear to a wide audience. Our results show that defining and providing detailed descriptions of domains in an iterative manner over time can help to clarify domains and lead to a consensus by various groups such as PRPs, clinicians and researchers. Consensus is a particular achievement in the field of SDM, which is a complex field in which there are many concepts that may be difficult to understand and agree upon.

Having clear definitions and detailed descriptions will help our group to search the literature to identify candidate instruments to assess

our domains (i.e., domain match), which will inform future development and consensus on the Core Outcome Measurement Set.

Strengths and limitations

We sent the survey exclusively to WG members to ensure feasibility. The group has wide geographical representation and includes PRPs/caregivers, clinicians and researchers. However, our results may not represent the views of individuals from low-and middle-income countries and Asia, although some of our WG members worked in these regions. We may not have been able to engage PRPs with lower socioeconomic status and limited health literacy, and we did not have strong representation from allied health providers. Future work should aim to include these under-represented groups.

Conclusion

Our WG reached consensus on the definitions and descriptions of the domains of the Outcome Measures in Rheumatology (OMERACT) core domain set for rheumatology trials of SDM interventions. Agreement on the definitions and descriptions provides the foundation to identify instruments to measure each domain for inclusion in the Core Outcome Measurement Set.

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