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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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Abstract

Objective:

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

Methods:

The process followed the OMERACT Filter 2.1 methodology, and used consensus-building methods ~~grounded in a patient-oriented approach~~, with patients involved since the inception. After developing the draft core domain set in previous steps, w~~W~~e conducted five steps: (i) improving the draft core domain set; (ii) developing and disseminating white-board videos to promote its understanding; (iii) conducting an ~~international~~ 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 answered the electronic survey (62% ~~of~~ 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:

~~Our collaborative process with an international group of stakeholders~~ We achieved consensus among an international group of stakeholders on the OMERACT core domain set for ~~SDM interventions in~~ rheumatology trials of SDM interventions. Future research will develop the Core Outcome Measurement Set.

Key words:

OMERACT, shared decision making, core domain set

Abbreviations:

OMERACT: Outcome Measures in Rheumatology
SDM: shared decision making
~~PDAs: patient decision aids~~

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PRPs: patient research partners

Clinical significance:

Prior to this study, there had been no consensus on the OMERACT core domain set for shared decision making 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.

1. INTRODUCTION

Shared decision making (SDM) is central to patient-centered care ~~[1] and~~ since it facilitates the inclusion of patient values, preferences, and circumstances in decision-making, thus helping patients partake in decision-making and in their care in a meaningful way [1,~~is at the crossroads between evidence-based medicine and patient-centered care [~~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 ~~(PDAs)~~ [8]. Despite the incorporation of SDM into rheumatology guidelines and trials of patient decision aids~~PDAs~~ in rheumatology, there remains a lack of consensus among stakeholders (e.g., clinicians, patients and researchers) on how to standardize the measure of the effectiveness and safety of SDM interventions [8,9]. Another research group has identified domains to assess the effectiveness of patient decision aids~~PDAs~~ [10]. However, most concern the SDM process, and only one assesses an outcome (i.e., improved match between the chosen option and the 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. 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~~SDM interventions in rheumatology trials~~.

2. MATERIAL AND METHODS

2.1 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.

2.2 Steps

2.2.1 Improving the draft core domain set

The working group met on several occasions to review the findings from the interviews [13] and other previous steps to. ~~The group modified the draft core domain set to~~ ensure the accuracy and clarity of the draft core domain set~~, and updated the White Paper accordingly~~.

2.2.2 Developing and disseminating white-board videos

To ensure that 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, SDM outcomes and the draft core domain set. These videos aimed to summarize the information from the White Paper in a concise and visual manner. Videos were posted on YouTube, social media (i.e., Facebook, Twitter) and on the OMERACT website to promote understanding of the core domain set and to encourage individuals to participate in the next steps.

2.2.3 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 to the survey 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 the 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 ~~in the core set~~ using a 9-point Likert scale, and asked if they wished to make modifications. For each outcome domain, the number of respondents and the proportion of responses with a rating of 7 to 9 (i.e., ~~considered to be~~ very clear and very 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.

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

The working group ~~made improvements to the core domain set based on~~reviewed modifications ~~that were~~ 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, but also ~~shows~~ domains that are mandatory in specific circumstances (i.e., disease-specific core set:

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Commented [TK2]: Should we add here that we added a domain? Then, in the results we can explain the whole core domain set a bit more to make it less repetitive between methods and results (comment 1, reviewer 2)?

outcomes that should be assessed in a specific rheumatic condition). The onion also includes other optional domains (i.e., important but not mandatory)~~outside of the core domain set~~, as well as 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 the justification for including each outcome domain; (c) a video of the plenary session to explain the steps taken, and the most recent modifications made to the core domain set; and (d) online discussion boards to elicit feedback from individuals who intended to participate in the virtual workshops.

2.2.5 Conducting virtual workshops

The workshop was originally designed as a hybrid workshop, with both virtual and face-to-face participants. Due to the COVID-19 pandemic, the in-person meeting was cancelled, 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. In addition, the working group asked participants to view the 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 also asked 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 minutes, with 30 minutes used for breakout groups. Independent OMERACT trained-facilitators moderated break-out group discussions, while reporters took notes and content experts answered questions in each breakout group. After the breakout groups, reporters presented a summary of each group's discussions to the larger workshop 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.

3. RESULTS

3.1 Draft core domain set

Based on discussions among the working group, we made minor changes to domains presented in the last step [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 their definitions). The White Paper was revised accordingly.

~~and a reminder that harms should be assessed in all OMERACT core domain sets, we added a domain that represents potential harms of SDM interventions in the draft core domain set (see Table 1). The White Paper was revised accordingly.~~

3.2 White-board videos

The working group agreed that ~~general principles for designing the videos included the need to~~the videos should use a ~~lay language and anchor the SDM process and outcomes on a clinical case in which the choice depends on the patient's values. The white-board videos included a~~ plain language, visually-engaging presentation that capture~~d~~ the core domains, and present~~ed~~ a clinical case. One video explained the SDM process (video 1) [19] and the other video explained SDM outcomes and the draft core domain set (video 2) [20]. T~~Once posted on YouTube, t~~he videos were viewed about 200 times each on YouTube ~~each~~ by the time the survey was conducted.

3.3 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 stakeholders 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 some of the names and definitions of the domains (see Table 1).

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

Based on recommendations in the survey, ~~and~~ the working group ~~discussions~~clarified~~,~~ the domains~~names~~ and their definitions ~~of the domains were clarified~~ (see Table 1). The final core domain set was presented in the OMERACT "onion" (see Figure 1) with the six mandatory domains that had shown high relevance in previous steps, no domains that were deemed optional and three domains that were found promising but that need further evidence to be considered for inclusion [12,13].

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P~~The one-page summary and evidence summary were provided in the p~~re-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.

3.5 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 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.

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. ~~Endorsed d~~Domains that are deemed mandatory to assess in trials of SDM interventions 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. This core domain set is unique and focuses on outcomes of SDM interventions, both benefits and harms.

Our work showed that the strategies that were co-developed with PRPs, such as white-board videos, summaries and discussion boards, helped promote understanding of a complex and unconventional new core domain set. In fact, 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, as well as a high level of confidence in their knowledge.

We engaged key stakeholders within our working group, including PRPs, who were involved, not just as participants, but as leaders within the working group, thus helping to foster meaningful patient engagement [22].

~~These strategies~~This approach ~~helped~~ engage stakeholders in the consensus-building process, indicated by the high level of participation in the survey and workshops, 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). ~~Our~~ results 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]. They also show that ~~.~~

~~Our approach also succeeded in engaging key stakeholders within our working group, including PRPs, which is crucial to ensuring future buy-in by research and patient communities. PRPs were involved, not just as participants, but as leaders within the working group, thus helping to foster meaningful patient engagement [22]. This may have facilitated patients/caregivers' participation, as well as their endorsement of the core domain set.~~

~~Our experience suggests that holding virtual workshops facilitated participation compared to the in-person workshop at OMERACT 2016. This is especially true for patients/caregivers whose representation was four times higher in 2020 (32% of 149 participants in 2020 vs. 8% of 96 participants in 2016).~~

~~Overall, using~~ virtual consensus-building strategies ~~helped to~~can be used to gain consensus with representation from various key stakeholders ~~at a time where the COVID-19 pandemic made it difficult to conduct research~~.

Limitations

Despite concerted efforts to engage patients and caregivers throughout the process, there are populations we likely did not reach, such as patients and caregivers from across all sociodemographic and language groups, or those with technology barriers or lack of access to the Internet. Future work will address these shortcomings.

5. CONCLUSION

The use of 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 to refine, clarify and ensure proper understanding of this complex and unconventional core domain set. The core domain set showed a high level of 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.

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

Domains before the electronic survey	Comments from survey participants	Domains after the electronic survey (proposed for final vote at the workshops)

Knowledge of **all** options, their potential benefits and **risks** Description: The shared decision making intervention helps patients understand the available options and their potential benefits, as well as **risks**. It also helps them to know the **probabilities** (chances) of benefits and **risks in an accurate manner**.	Survey participants felt that it was not realistic or feasible to give "all" the options. They also preferred the word "harms" which is used more commonly in trials. They felt that the word "probabilities" is confusing. They preferred a more lay-language term. The last part was felt to be redundant.	Knowledge of options, their potential benefits and **harms** Description: The shared decision making intervention helps patients understand the options and their potential benefits and **harms**. It also helps them to understand the **chances** of benefits and **harms**.
Choice of an option aligned with each patient's values and preferences 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.	Survey participants felt that the wording lacked clarity. They also wished to have examples of the "features" of treatment options.	**Chosen** option aligned with each patient's values/preferences 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 **(benefits, harms and practical aspects)** that they value most.
Confidence in the chosen option 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.	Survey participants felt that we should clarify that the best decision depends on what matters to each individual.	Confidence in the chosen option Description: 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.
Satisfaction with the decision-making process Description: The shared decision making intervention helps patients feel satisfied about the way they made the decision and about their level of involvement.	No comments in the survey	No change
Adherence to the chosen option Description: The shared decision making intervention helps patients follow through with the chosen treatment option. It means they start using the option they chose.	Survey participants felt that adherence is not just starting to use a treatment option but continuing as well.	Adherence to the chosen option Description: 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.
Potential negative consequences **(e.g., difficult to use, stressful, costly, time-consuming)**	A few survey participants thought that the "potential negative consequences"	Potential negative consequences **of the SDM intervention**

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.	pertained to treatment options and not the SDM intervention.	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.

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

~~Table legend: This table presents the core domain sets before and after the electronic survey, along with comments from survey participants.~~

Table 2. Characteristics of participants in the electronic survey

Types of characteristics	Participants
	~~n~~ (%) (n=167)
Sex	**~~n=167~~**
Female	~~137 (~~82~~)~~
~~Male~~	~~30 (18)~~
Experience in SDM	**~~n=166~~**
No experience in SDM	~~88 (~~53~~)~~
Limited (i.e., participated in a shared decision making intervention study)	~~44 (~~27~~)~~
Experienced (i.e., developed shared decision making interventions)	~~34 (~~20~~)~~
Role*	**~~n=166~~**
Patient	~~105 (~~63~~)~~
Clinician	~~59 (~~36~~)~~
Researcher	~~37 (~~22~~)~~
Caregiver (*e.g.*, family member of individual with arthritis)	~~7 (~~4~~)~~
Member of Industry	~~3 (~~2~~)~~
Policy Maker	~~1 (~~1~~)~~
Other (e.g., consumer advocates, patient partners, research students)	~~9 (~~5~~)~~
Geographic location	**~~n=164~~**
Canada	~~49 (~~30~~)~~
United States of America	~~24 (~~15~~)~~
United Kingdom	~~19 (~~12~~)~~
The Netherlands	~~13 (~~8~~)~~
Other European Countries	~~40 (~~24~~)~~
Australia/New Zealand	~~14 (~~9~~)~~
Asia	~~3 (~~2~~)~~
Other	~~2 (~~1~~)~~

n: number of participants

* Some respondents had more than one role

~~Table legend: This table presents the demographic and disease-related characteristics of individuals who responded in the electronic survey.~~

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

Domains	Question	Results (n (%)*)		
		Patients / Caregivers** (n=87***)	Clinicians / Researchers and others (n=57***)	Total (n=144***)
Knowledge of options	Relevance	**n=87** 81 (93)	**n=57** 55 (96)	**n=144** 136 (94)
	Clarity	**n=86** 79 (92)	**n=57** 53 (93)	**n=143** 132 (92)
Choice of an option aligned with each patient's values and preferences	Relevance	80 (96)	53 (93)	133 (95)
	Clarity	76 (90)	50 (89)	126 (90)
Confidence in the chosen option	Relevance	72 (88)	54 (95)	126 (91)
	Clarity	73 (88)	52 (91)	125 (89)
Satisfaction with the decision-making process	Relevance	79 (96)	47 (84)	126 (92)
	Clarity	77 (95)	51 (89)	128 (93)
Adherence to the chosen option	Relevance	76 (93)	48 (86)	124 (91)
	Clarity	73 (89)	46 (82)	119 (86)
Potential negative consequences	Relevance	66 (81)	45 (80)	111 (81)
	Clarity	68 (84)	43 (77)	111 (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.

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

Table legend: This table presents the relevance and clarity of each domain according to patients/caregivers, clinicians/researchers and others, as well as the total sample of participants in the electronic survey.

Table 4. Final OMERACT core domains and definitions

Domains and Definitions ~~Definitions~~
Knowledge of options, their potential benefits and harms The shared decision making intervention helps patients understand the options and their potential benefits and harms. It also helps them to understand the chances of benefits and harms. ~~The shared decision making intervention helps patients understand the options and their potential benefits and harms. It also helps them to understand the chances of benefits and harms.~~
Chosen option aligned with each patient's values/preferences 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. ~~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.~~
Confidence in the chosen option 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. ~~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.~~
Satisfaction with the decision-making process The shared decision making intervention helps patients feel satisfied about the way they made the decision and about their level of involvement. ~~The shared decision making intervention helps patients feel satisfied about the way they made the decision and about their level of involvement.~~
Adherence to the chosen option 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. ~~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.~~
Potential negative consequences of the SDM intervention The shared decision making intervention may have potential negative consequences, such as being difficult to use, stressful, or take too much time or money.

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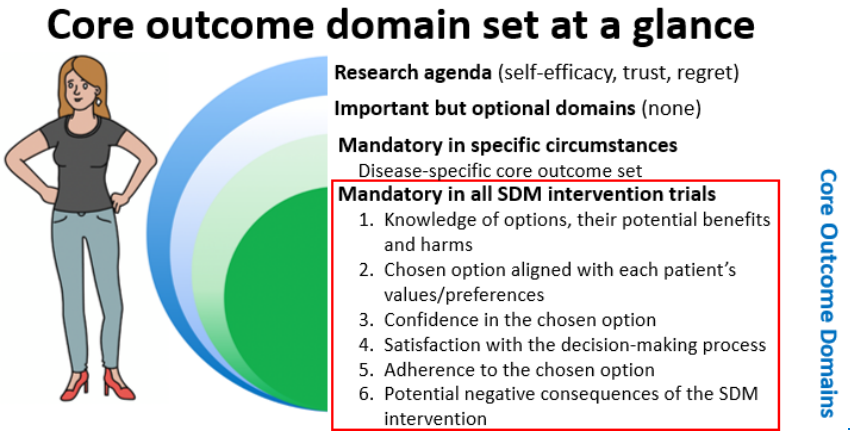
~~The shared decision making intervention may have potential negative consequences, such as being difficult to use, stressful, or take too much time or money.~~

~~Table legend: This table presents the final OMERACT core domains for SDM interventions and their definitions.~~

Figure 1. Final OMERACT SDM Core Domain Set



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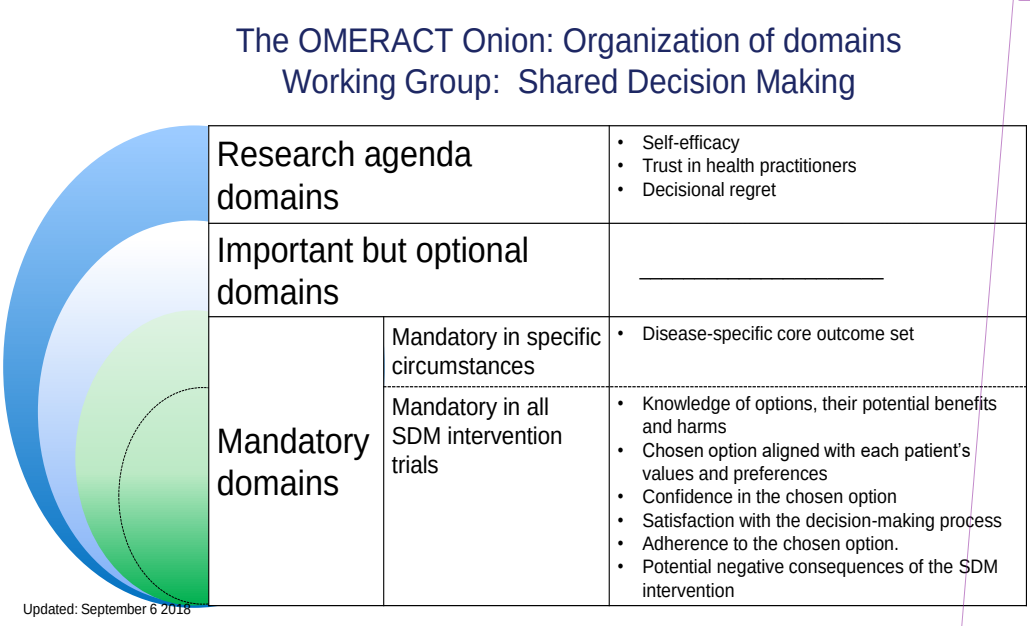

Figure legend: This figure presents the OMERACT onion with the final OMERACT core domain set for SDM interventions.

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Conflict of Interests

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 Voshaar, 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 Jayatilleke, 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.

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