OMERACT Development of a Core Domain Set of Outcomes for Shared Decision-making Interventions

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ABSTRACT. ***Objective.*** The Outcome Measures in Rheumatology (OMERACT) Shared Decision Making (SDM) Working Group aims to determine the core outcome domain set for measuring the effectiveness of SDM interventions in rheumatology trials.

Methods. A white paper was developed to clarify the draft core domain set. It was then used to prepare for interviews to investigate reasons for lack of consensus on it and to suggest further improvements.

Results. OMERACT scientists/clinicians (n = 13) and patients (n = 10) suggested limiting the core domain set to outcome domains, removing process domains, and clarifying remaining domains.

Conclusion. A revised core domain set will undergo further consensus-building. (J Rheumatol First Release February 15 2019; doi:10.3899/jrheum.181071)

Key Indexing Terms:
OMERACT RHEUMATIC DISEASES OUTCOMES

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There has been an increasing interest from patients to engage in shared decision making (SDM)[1] and there is an ethical imperative to do so[2]. The incorporation of SDM is also a recommended standard of care in rheumatology practice[3,4,5,6]. SDM is defined as a process by which patients and healthcare professionals work together to make decisions based on the best available evidence for treatment options while respecting each patient's values and preferences[7]. SDM is especially important when there is more than one medically reasonable option, and the optimal choice depends on what patients value most (e.g., types of harms, benefits)[8]. Patients who report having participated in SDM are likely to experience improved affective-cognitive outcomes, such as greater satisfaction and less decisional conflict (uncertainty)[9]. However, additional research is needed to clarify the effect of SDM on a wide range of outcomes including behavioral and health outcomes[9].

Interventions aimed at facilitating SDM include patient decision aids, decision coaching, question prompts, and healthcare providers' training[10,11,12,13]. Patient decision aids have been shown to improve knowledge of treatment options and accurate risk perceptions, clarify patients' values and preferences, and facilitate patient participation in decision making[10]. Also, decision coaching improves knowledge and patient satisfaction[11], while question prompts improve satisfaction[12]. There is a need for more research examining the effectiveness of interventions to facilitate the practice of SDM by healthcare professionals[13]. Despite the great potential of SDM interventions to improve patient involvement and management of various rheumatic conditions[14,15,16], lack of consensus on which outcomes to measure creates a barrier to further evaluation of SDM interventions and their implementation in clinical practice.

The Outcome Measures in Rheumatology (OMERACT) SDM Working Group (WG) is developing consensus on a core domain set of outcomes for measuring the effectiveness of SDM interventions in rheumatology clinical trials. Following the OMERACT Filter 2.1 multistep methodology[17,18,19], the WG developed a draft core domain set of SDM process and outcome domains based on a systematic review and a nominal group process conducted at the OMERACT 2014 meeting[20]. In 2016, an international electronic Delphi survey was conducted among patients, caregivers, clinicians, and researchers to refine the domains of the OMERACT draft core domain set[21]. This draft core domain set was then presented for voting by attendees at the OMERACT 2016 meeting. Despite high levels of endorsement of the draft core domain set in the premeeting Delphi survey, it did not receive the needed 70% at the voting in the plenary session, and thus this version was not endorsed at the OMERACT 2016 meeting. Possible reasons for this lack of endorsement include (1) challenges related to comprehension of the core domain set because of the lack of familiarity of OMERACT participants with SDM concepts; (2) confusion between domains of the core domain set that assess the SDM process rather than its outcomes, which are usually the focus of OMERACT core domain sets; and (3) lower representation of patients at the final plenary vote compared with the prior Delphi survey, combined with the possible differences between patients' and clinicians' levels of endorsement.

These challenges highlighted the need to clarify the relevance, development process, and content of the draft SDM intervention core domain set, as well as to improve it, with input from both patients and clinicians/scientists, in a way that addresses the potential reasons why consensus was not achieved at OMERACT 2016.

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MATERIALS AND METHODS

First, the WG endeavored to clarify the relevance, development process, and content of the draft core domain set of outcomes of SDM interventions in the form of a draft white paper. Next, the draft white paper was used to help prepare patients and clinicians/researchers for interviews to gather their perspective on how to improve the core domain set. Finally, their feedback was used to develop an improved draft core domain set and a final white paper.

1. Development of the draft white paper. A draft white paper was developed with the input of key participants (i.e., patients and clinicians/scientists) within our research team using online group discussions and individual interviews. They were asked to identify information that was necessary to clarify the background, development process, and terms used in the draft SDM intervention core domain set.

The elements included in the draft white paper were (1) background information on SDM and its importance in rheumatology clinical trials, which included a definition of SDM; (2) background on SDM interventions, including the evidence for patient decision aids and decision coaching and links to some examples; (3) rationale and overall goal of the OMERACT SDM WG, including an example of a research question asked in a trial to which the core domain set would apply; (4) previous work and hypotheses generated to explain the lack of consensus on the draft core domain set; (5) draft core domain set, including information on the level of importance of each domain in previous phases of our work (e.g., 2016 Delphi survey, OMERACT 2016 workshop) and from other organizations such as the International Patient Decision Aid Standards (IPDAS), i.e., core set of domains to assess the effectiveness of patient decision aids[22]; and (6) future steps. The draft core domain set in the white paper presented both domains related to the SDM process as well as SDM outcome domains, but in 2 separate categories to clarify the distinction between these 2 types of domains (falling under the OMERACT heading of patient-reported life impact outcomes; Figure 1). We defined "process domains" as domains that represent steps of the SDM process (e.g., patients receive information about the options and their features). We defined "outcome domains" as domains that are expected to change as a result of an SDM intervention (e.g., patient knowledge of the options and their features).

2. Interviews. Key participants from various OMERACT WG were identified using the list of OMERACT conference attendees and were contacted by e-mail. They received information about the project, and the Research Ethics Board of the Children's Hospital of Eastern Ontario Research Institute ruled that their oral consent to participate was sufficient because no personal information was gathered. The board approved the study (CHEOREB#16/07X). They were asked to participate in semistructured interviews by telephone or by GoToMeeting (an online meeting and video conferencing tool) to determine how to improve the clarity and relevance of the revised draft core domain set, and by extension, to inform the white paper. The draft white paper was sent to participants with instructions to read it before the interview. The same interviewers conducted all interviews. First, an interviewer explained the goal of the WG and of the core domain set, and summarized results from the previous steps conducted by the WG. Interviewers then used a guide with open-ended questions asking about the clarity and relevance of the core domain set, as well as eliciting recommendations for modifications to the core domain set and white paper. Interviews were audio-recorded and transcribed verbatim. Field notes were taken by the interviewer. Transcripts and field notes were included in a process of content analysis using NVivo 11 software. Themes were identified from the field notes and transcripts. Feedback was used to improve the white paper and the core domain set to address participants' concerns.

RESULTS

Of a sample of 25 OMERACT members, 23 participated in interviews, of which 13 were scientists/clinicians and 10 were patients. Two individuals were unable to participate. Nine participants (3 patients) were from North America, 9 from Europe (5 patients), and 5 from Australia (2 patients). Patients had a variety of rheumatic conditions (e.g., rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Behçet disease, myositis). Interview duration varied between 30 and 75 min.

The group co-producing this manuscript represents people involved in OMERACT as well as researchers, patient representatives, and policy makers from several countries who have an interest in SDM and core outcomes. Co-producing research is an approach in which all these people work together and share power and responsibility throughout the duration of the project[23]. This includes the generation of knowledge and co-authorship based on substantive input from the individuals' lived experiences and/or expertise on resulting abstracts, manuscripts, and other dissemination materials[23].

Feedback on the draft core domain set. All participants agreed that SDM is vital to patient care and that an SDM intervention core outcome domain set fits within the OMERACT mandate. However, many participants acknowledged that it differs from the usual OMERACT core domain set, which is usually for a disease. SDM outcome domains are also different from what OMERACT members are accustomed to (i.e., condition-specific health outcomes). Participants expressed diverse views of how they perceived SDM and its implementation, based on their own personal experiences, even though they felt that the white paper helped them to understand the relevance, development process, and content of the core outcome domain set. They recommended that the WG acknowledge the unique features of SDM and improve the clarity of the core domain set when presenting it to OMERACT members.

All participants felt that domains related to the process and outcomes of SDM were important to measure but should be clearly distinguished from one another. Most participants mentioned that, because OMERACT focuses on outcome rather than process domains, current efforts should aim to generate outcome domains. Future work will help determine the need for a core set of process domains.

When looking at outcome domains in more detail, most participants felt that all SDM outcome domains were relevant, but suggested regrouping some of them. For example, a few participants suggested that the domain entitled "knowledge of the options" should include accurate risk perceptions, rather than having it as a separate core domain. We decided to merge them at the present time. Also, a few participants felt that "adherence to the chosen option" should be included in the middle circle of the core domain set, meaning that it can be measured in trials of SDM interventions but is not essential, while some wanted to include it in the inner circle, meaning that it is essential. A few participants recommended modifying the name of this domain to "implementation of the chosen option" because they feared

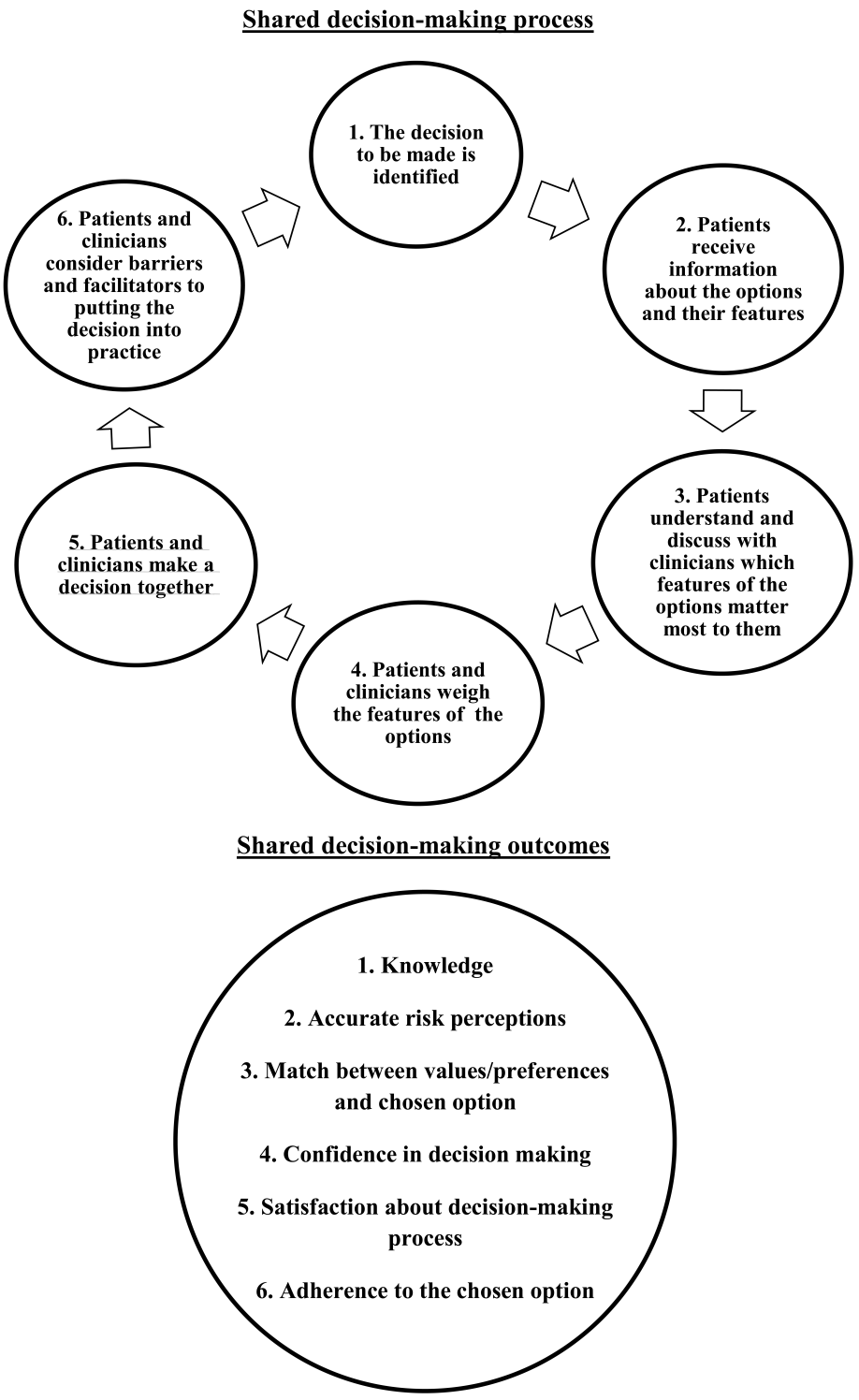

Figure 1. The draft core domain set divided into process and outcome domains presented in the white paper.

the negative connotation that patients follow their healthcare providers' choice and not their own. We decided to keep the term "adherence to the chosen option" in the inner circle at the present time, which means that they follow through with the chosen treatment option by starting to use the chosen option. Ongoing dialogue with the OMERACT Medication Adherence WG will help clarify this domain and the term to describe it.

In addition to minor changes in language and merging of some domains, participants recommended the addition of descriptions for each domain. We added these descriptions for each domain of the core domain set. Finally, because OMERACT members are not as familiar with SDM outcome measures, they suggested providing a few examples of SDM outcome measures to make the draft core domains more understandable. We will work on adding these in the future.

Revised draft core domain set. Based on participants' feedback, the draft core domain set was revised (Figure 2). It includes knowledge of all available options, their potential benefits, and risks; choice of an option aligned with each patient's values/preferences; confidence in the decision made; satisfaction with the decision-making process; and adherence to the chosen option.

Development of the final version of the white paper. Based on the interviews, a final version of the white paper was created (https://omeract.org). Changes made in this version include (1) simplification and clarification of the background information on SDM; (2) mention of the emphasis placed on SDM outcome rather than process domains; and (3) presentation of the revised draft core domain set with a description of each domain.

A few participants also suggested creating a more concise document (such as a one-pager) and providing OMERACT members with audiovisual material to make the core domain set more tangible and understandable, and to facilitate the endorsement of the core domain set.

DISCUSSION

Developing the white paper with our WG helped us to clarify the relevance, development process, and content of the draft core domain set. Discussing it with key participants in OMERACT has also helped us to further our understanding of the challenges to reaching consensus on the draft SDM intervention core outcome domain set. Challenges include that the SDM process and its outcome domains do not reflect a typical OMERACT core set. In addition, participants revealed significant variation in the understanding of SDM and the core domain set. Our findings provide directions for the SDM WG on how to improve and simplify the draft core domain set to facilitate its endorsement.

The revised draft core domain set should address the challenges experienced in gaining consensus at OMERACT 2016. First, explaining and defining SDM, SDM interventions, and the core domain set in a clear and concise format may increase understanding. Second, restricting the revised core domain set to outcome domains as opposed to both process and outcome domains should clarify these types of domains and better align with the OMERACT framework.

The revised draft core domain set differs from the IPDAS criteria to evaluate effectiveness of decision aids, which uses different language and includes both process and outcome domains[22]. However, our current research strictly followed the OMERACT methodology and shows the importance of modifying the core set to suit everyone's needs, which required a focus on outcome domains. Obtaining both

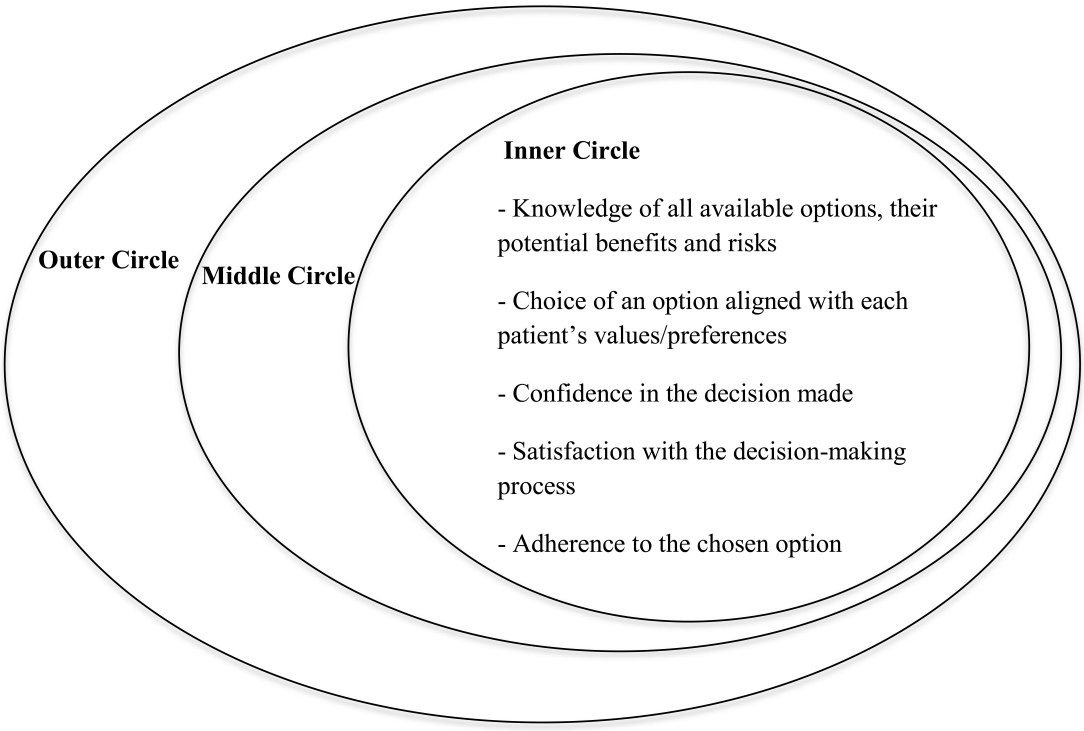

Figure 2. The revised draft core outcome domain set after the conduct of the interviews. Outer circle (research agenda): outcome domains that require further investigation; middle circle: outcome domains that are strongly recommended to measure but not mandatory; inner circle: outcome domains that are mandatory to measure in all clinical trials of shared decision-making interventions.

scientist/clinicians' and patients' input is crucial because they will ultimately conduct, appraise, and use the research on SDM interventions in rheumatology. The revised draft core domain set will be taken forward for further consensus-building. Disseminating the improved white paper as well as a more concise document should help to achieve the endorsement of the core outcome domain set.

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