

Development of a Draft Core Set of Domains for Measuring Shared Decision Making in Osteoarthritis: An OMERACT Working Group on Shared Decision Making

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ABSTRACT. Objective. Despite the importance of shared decision making for delivering patient-centered care in rheumatology, there is no consensus on how to measure its process and outcomes. The aim of this Outcome Measures in Rheumatology (OMERACT) working group is to determine the core set of domains for measuring shared decision making in intervention studies in adults with osteoarthritis (OA), from the perspectives of patients, health professionals, and researchers.

Methods. We followed the OMERACT Filter 2.0 method to develop a draft core domain set by (1) forming an OMERACT working group; (2) conducting a review of domains of shared decision making; and (3) obtaining opinions of all those involved using a modified nominal group process held at a session activity at the OMERACT 12 meeting.

Results. In all, 26 people from Europe, North America, and Australia, including 5 patient research partners, participated in the session activity. Participants identified the following domains for measuring shared decision making to be included as part of the draft core set: (1) identifying the decision, (2) exchanging information, (3) clarifying views, (4) deliberating, (5) making the decision, (6) putting the decision into practice, and (7) assessing the effect of the decision. Contextual factors were also suggested.

Conclusion. We proposed a draft core set of shared decision-making domains for OA intervention research studies. Next steps include a workshop at OMERACT 13 to reach consensus on these proposed domains in the wider OMERACT group, as well as to detail subdomains and assess instruments to develop a core outcome measurement set. (First Release April 15 2015; J Rheumatol 2015;42:2442-7; doi:10.3899/jrheum.141205)

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The treatment of various rheumatic conditions such as osteoarthritis (OA) should be based on a shared decision between patient and health professionals^{1,2,3,4,5}. Shared decision making is a process in which both patient and health professional make a decision, taking into account the best evidence of available treatment options and the patient's

values and preferences⁶. Despite the importance of shared decision making for delivering patient-centered care in rheumatology, health professionals are sometimes reluctant to put it into practice because of misconceptions such as it being too time-consuming for the busy clinic, or not being compatible with clinical practice guidelines⁷. However, such claims are unsupported by evidence^{8,9,10}, and shared decision making interventions have been shown to reduce decisional conflict (in terms of feeling uninformed and unclear about personal values), facilitate patient participation in decision making, and reduce overuse of high-risk interventions⁹.

One of the barriers to studying and using shared decision-making interventions in rheumatology is a lack of consensus on how to measure their effectiveness in rheumatology studies, both concerning the shared decision-making process and outcomes.

The aim of this Outcome Measures in Rheumatology (OMERACT) working group is to determine the core set of domains for measuring shared decision making in intervention studies in adults with OA, from the perspective of patients, health professionals, and researchers.

MATERIALS AND METHODS

We followed the OMERACT Filter 2.0¹¹ to develop a draft core domain set, which consisted of (1) forming an OMERACT working group; (2) conducting a review of domains of shared decision making; and (3) obtaining the opinions of those involved using a modified nominal group process held at a session activity at the OMERACT 12 meeting.

Forming an OMERACT working group. Individuals from various groups, including patient research partners (PRP) with rheumatic conditions, health professionals, and researchers, were invited to participate in the working group and in a session activity at the OMERACT 12 meeting.

Review of domains of shared decision making. We started by using the most recently published theory analysis of shared decision-making conceptual models¹² and identified more recent published shared decision-making models. We grouped some of the key concepts of shared decision making into domains and developed a draft core set checklist of potential shared decision-making domains (Table 1).

Participant opinions. The opinions of participants on the draft core set of shared decision-making domains to be measured and other potential domains were explored using a modified nominal group process held at a session activity at the OMERACT 12 meeting. To help participants identify domains, 2 clinical vignettes with contrasting levels of shared decision making (available on www.omeract.org) were developed and assessed using the draft core set checklist of potential shared decision-making domains identified from the literature.

Development of clinical vignettes. Based on methods proposed by members of the group¹³, the working group developed 2 clinical vignettes featuring a rheumatology consultation of a patient with OA who is considering nonsteroidal antiinflammatory drugs for pain management. One vignette (high shared decision making) used the optimal shared decision-making approach, and the other used a lower level of shared decision making (low shared decision making), as confirmed by their appraisal using valid and reliable instruments: the Brief Decision Support Analysis Tool^{14,15} and the Observing Patient Involvement in Decision Making¹⁶ scales. Three PRP and 5 experts in rheumatology and shared decision making revised the vignettes to ensure content validity and clarity. The high shared decision-making vignette was slightly longer than the low shared decision-making vignette, which is a limitation considering there is no clear difference in the duration

Table 1. Checklist of core set of shared decision-making domains presented to participants.

Are the following elements present in the vignettes?	Low SDM Vignette	High SDM Vignette
Identifying the decision		
The decision to be made is pointed out		
Exchanging information		
The treatment options are listed and their pros and cons explained		
Clarifying patients' views		
The patients' feelings about the pros and cons of the options are discussed		
Deliberating		
The pros and cons of the options are weighted and the feasibility of the options is considered		
Making the decision		
A decision is made or postponed		
Putting into practice		
The steps are arranged to put the decision into practice		
Effect of the decision		
Comments		

SDM: shared decision making.

of consultation when shared decision making is implemented in practice. The high shared decision-making vignette included the use of a summary of evidence, which is embedded in a decision aid available from <http://ow.ly/JmjGD>.

Conduct of a modified nominal group process. Individuals from various groups were invited to participate in the modified nominal group process led by members of the working group at the session activity at the OMERACT 12 meeting. The vignettes were performed as skits. Then, in pairs, participants were asked to identify differences between the vignettes using the draft core set of domains checklist. Each participant was asked, on 3 consecutive occasions, to suggest domains in the checklist or any additional domains that he or she found important to assess. These domains were displayed, and participants were given 10 stickers to attribute to the various domains (from the core set and suggested new domains). The color of the stickers differed between PRP and health professionals/researchers.

RESULTS

Composition of the OMERACT Working Group

The working group included 28 individuals from the various groups, including 9 PRP with rheumatic conditions and 19 health professionals and researchers from Europe, North America, and Australia. Health professionals involved in the working group were rheumatologists, family practitioners, nurses, and rehabilitation professionals. Researchers were health professionals/researchers in the field of shared decision making, knowledge transfer, systematic reviews, instrument and intervention development, and epidemiology. In all, 26 people participated in the session activity, of which 5 were PRP, and 21 were rheumatology health professionals and/or researchers from Europe, North America, and Australia.

Review of Shared Decision-making Domains

A theory analysis of shared decision-making conceptual models¹², in which domains of shared decision making were synthesized according to 3 systematic reviews^{6,17,18}, showed that patients were included in the development process in

only 2 of 15 shared decision-making conceptual models^{19,20}; and no model included rheumatology patients in their development and testing. We also identified a more recently published interprofessional shared decision-making model²¹.

The initial draft core set checklist of potential shared decision-making domains to be measured was identified from the literature (Table 1): (1) identifying the decision; (2) exchanging information; (3) clarifying patients' views; (4) deliberating; (5) making the decision; (6) putting the decision into practice; and (7) assessing the effect of the decision. Domains 1 to 6 represent the shared decision-making process, and domain 7 includes shared decision-making outcomes.

Opinions of the Participants

Participants in the session activity identified domains that can be classified in the following core areas of the OMERACT Filter 2.0: Pathophysiology (called "process" here), as well as life impact and resource use (called "outcomes" or "impact" here). Other suggested concepts are contextual factors. The most important domains, according to the participants, were exchanging information, clarifying views, assessing the effect of the decision, and deliberating (Table 2). Exchange of information included subdomains of presentation of unbiased evidence-based information on the risks and benefits of options, as well as uncertainties, in a format and language patients understand. The clarification of patients' understanding was another important element. For clarification of views, it was noted that patients' values and expectations were rated as important mostly by PRP. However, health professionals/researchers also suggested the importance of considering their own views. Under the effect of the decision domain several subdomains were suggested, including patient health outcomes, adequate knowledge and informed consent, trust in the healthcare system, and time

Table 2. Subdomains of shared decision making with their number of votes.

Domains and Subdomains	No. Votes (10 per person)		
	Patient Research Partners, N = 5 (weighted opinion)*	Health Professionals / Researchers, N = 21 (weighted opinion)*	Total, N = 26 (weighted opinion)*
Exchanging information	13 (26%)	52 (25%)	65 (25%)
General domain	6 (12%)	12 (6%)	18 (7%)
Presenting the evidence for the risks and benefits of options and uncertainties in an unbiased manner	0 (0%)	18 (9%)	18 (7%)
Tailoring the information (format and language patients understand)	4 (8%)	15 (7%)	19 (7%)
Clarifying patient understanding	3 (6%)	7 (3%)	10 (4%)
Clarifying views	13 (26%)	35 (17%)	48 (18%)
General domain	6 (12%)	12 (6%)	18 (7%)
Clarifying patients' values	4 (8%)	6 (3%)	10 (4%)
Clarifying patients' expectations regarding the courses of action	3 (6%)	7 (3%)	10 (4%)
Clarifying health practitioners' views (global assessment of the patient)	0 (0%)	10 (5%)	10 (4%)
Assessing the effect of the decision	7 (14%)	39 (19%)	46 (18%)
General domain	1 (2%)	10 (5%)	11 (4%)
Patient satisfaction, comfort with decision	1 (2%)	4 (2%)	5 (2%)
Patient informed consent, understanding of information	2 (4%)	12 (6%)	14 (5%)
Health outcomes	1 (2%)	4 (2%)	5 (2%)
Trust in healthcare system	0 (0%)	4 (2%)	4 (2%)
Health practitioner's liability	1 (2%)	1 (0%)	2 (1%)
Time and resources needed	1 (2%)	4 (2%)	5 (2%)
Deliberating	6 (12%)	27 (13%)	33 (13%)
General domain	1 (2%)	8 (4%)	9 (3%)
Considering the benefit/risk ratio of the options	3 (6%)	11 (5%)	14 (5%)
Considering the feasibility of the options	2 (4%)	8 (4%)	10 (4%)
Identifying the decision	2 (4%)	9 (4%)	11 (4%)
Making the decision	0 (0%)	6 (3%)	6 (2%)
Putting the decision into practice	0 (0%)	4 (2%)	4 (2%)
General domain	0 (0%)	4 (2%)	4 (2%)
Preparing plans for implementation and followup	0 (0%)	0 (0%)	0 (0%)

*Analyzed as the no. votes/(participants × 10).

and resources used. The deliberation process included subdomains such as weighting the benefit/risk ratio for the options, as well as considering whether treatments are feasible and “fit into the patients’ lives.” Identifying the decision, making the decision, and putting the decision into practice received fewer votes. The resulting draft core set of domains for measuring shared decision making is as follows: (1) identifying the decision; (2) exchanging information; (3) clarifying views; (4) deliberating; (5) making the decision; (6) putting the decision into practice; and (7) assessing the effect of the decision.

Participants also suggested contextual factors that should be measured, including general features of the setting, and characteristics of the people involved in the decision that may influence the shared decision-making process (Table 3). The most important were the establishment of a partnership between patients and health professionals. Health professionals’ assertiveness was important to health professionals/researchers, while consideration of the patient’s sociodemographic characteristics and social support was important to PRP.

DISCUSSION

This working group, which included an interdisciplinary group of patients, health professionals, and researchers, successfully developed the draft core set of domains for measuring shared decision making in intervention studies in adults with OA. More specifically, most domains identified in the literature were endorsed by this working group, but there was variation in the degree of support for each one. The domains rated as important across groups were exchanging information, clarifying views, assessing the effect of the decision and deliberating, which was consistent with key concepts found in a systematic review of shared decision-making domains⁶ and in the 2010 theory analysis of shared decision-making conceptual models¹². These domains were also included in the more recent interprofessional shared decision-making model²¹. Overall, our results led us to make 4 main observations.

First, all participant PRP, health professionals, and researchers found the exchange of information to be the most important domain, which may be explained by the desire for/interest in knowledge translation of evidence among the

Table 3. Contextual factors of shared decision making with their number of votes.

Contextual Factors	No. Votes (10 per person)		
	Patient Research Partners, N = 5 (weighted opinion)*	Health Professionals / Researchers, N = 21 (weighted opinion)*	Total, N = 26 (weighted opinion)*
Establishing partnership and mutual respect	4 (8%)	28 (13%)	32 (12%)
General domain	1 (2%)	4 (2%)	5 (2%)
Health professionals' empathy and desire to let patients speak (by using open-ended questions, empathetic non-verbal language)	2 (4%)	22 (10%)	24 (9%)
No time pressure	1 (2%)	0 (0%)	1 (0%)
Patients' ability to speak their mind	0 (0%)	2 (1%)	2 (1%)
Considering patient sociodemographic context and social support	4 (8%)	4 (2%)	8 (3%)
Health professional's assertiveness	1 (2%)	6 (3%)	7 (3%)
Educational material and decision aids	0 (0%)	0 (0%)	0 (0%)
Total	9 (18%)	38 (18%)	47 (18%)

*Analyzed as the number of votes/(participants × 10)

public and scientific community, and reflected in the number of suggested subdomains. Clarifying patients' values and expectations was identified as important, mostly by PRP, while health professionals felt that their own views were also important, as identified in other shared decision-making conceptual models^{6,12}. This is congruent with the call for ending the misdiagnosis of preferences²², which argues that clinicians who do not assess patients' values and preferences may recommend inappropriate treatments, as if they were making a mistake in their diagnosis of the disease. Shared decision making relies on both evidence sharing and diagnosing of preferences.

Second, assessing the effect of the decision was found to be more important by health professionals/researchers than PRP, and focused on patient and system-level outcomes, but did not include other outcomes suggested in the literature such as adherence to the chosen option or agreement between patients and health professionals. Deliberating included subdomains that took into account the knowledge of the options, as well as individuals' views, characteristics, and context.

Third, identifying the decision, making the decision and putting the decision into practice may have received fewer votes because these steps are often assumed and/or overlooked¹², although they were shown to be important in other studies^{21,23}.

Finally, contextual factors are emphasized in the OMERACT Filter 2.0 and are especially important when assessing behavioral interventions. This was shown by the importance placed on assessing partnership between health professionals and patients, patients' own individual characteristics and context, as well as health professionals' perception of responsibilities and obligations to their patients, which were found in other shared decision-making models¹².

Next steps will be to develop a workshop at OMERACT 13 to reach consensus on these proposed domains in the wider OMERACT group, as well as to form subdomains and assess instruments to develop a core outcome measurement set.

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**Articles presented at the OMERACT 12 Conference,
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- Part 1: Pre-conference Meeting
- Part 2: Working Groups
- Part 3: Special Interest Groups I
- Part 4: Special Interest Groups II

Part 4 will appear in the January issue.