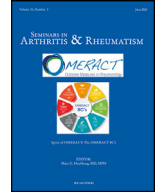




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## Endorsement of the domains of knee and hip osteoarthritis (OA) flare: A report from the OMERACT 2020 inaugural virtual consensus vote from the flares in OA working group

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## ARTICLE INFO

### Keywords:

Osteoarthritis  
Flare  
Measurement  
OMERACT

## ABSTRACT

**Objective:** Towards developing an instrument to measure knee and hip osteoarthritis (KHOA) flare, the Outcome Measures in Rheumatology (OMERACT) Flares in OA Working Group first sought to identify and define relevant domains of flare in KHOA.

**Methods:** Guided by OMERACT Filter 2.1, candidate domains were identified from data generated in interviews, in English or French, with persons with KHOA and health professionals (HPs) who treat OA. The first and second rounds of an online Delphi process with patients and HPs, including researchers, selected relevant domains. The third round provided agreement on the selected domains and their definitions. At the virtual OMERACT 2020 workshop, the proposed domains and their definitions were discussed in facilitated breakout groups with patients and HPs. Participants then voted, with consensus set at  $\geq 70\%$ .

**Results:** Qualitative interviews characterizing OA flare were completed with 29 persons with KHOA and 16 HPs. Content was analyzed and grouped into nine clusters. These candidate domains were included in two Delphi rounds, completed by 91 patients and 165 HPs then 50 patients and 116 HPs, per round, respectively. This resulted in selecting five relevant domains. A final Delphi round, completed by 38 patients and 89 HPs, provided agreement on these domains and their definitions. The OMERACT virtual vote included 27 patients and 106 HPs. The domains and their definitions were endorsed with  $\geq 98\%$  agreement. Domains include: Pain, Swelling, Stiffness, Psychological aspects, and Impact of symptoms, all defined “during flare”.

**Conclusion:** Using OMERACT methodology, we have developed five domains of KHOA flare that were highly endorsed by patients and HPs.

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## Introduction

The Outcome Measures in Rheumatology (OMERACT) *Flares in Knee and Hip Osteoarthritis* Working Group was established to develop an instrument to measure flare in knee and hip osteoarthritis (KHOA) using a data-driven, evidence-based process [1–3], and was an initiative endorsed by the Osteoarthritis Research Society International (OARSI). Flare is increasingly understood as an important aspect of the KHOA experience, and has been commonly used as an outcome in clinical trials [4]. However, there is no standardized definition of KHOA flare, nor established measurement instrument. Supporting this identified gap, the recently endorsed OMERACT-OARSI core domain set for KHOA placed flare in the research agenda [5].

Our prior research highlighted that KHOA flare is a multidimensional concept not simply an exacerbation of pain alone, and that the wide variation in flare definition in current use limits both the interpretation of research results and comparisons between studies [4]. Thus, with a view to developing an instrument to measure OA flare, we undertook preliminary work to generate and select its constituent relevant domains, and a definition of KHOA flare was proposed at OMERACT 2018 [6]. This paper reports subsequent work, culminating in the OMERACT 2020 virtual workshop where we sought consensus among patient and health professionals (HPs) on the domains of KHOA flare.

## Material and methods

This project entailed multi-stakeholder engagement across multiple countries in a series of steps towards instrument development [1, 7, 8], and followed the OMERACT process of domain development and selection [3]. The stages of the development of KHOA flare relevant domains are outlined below and are presented in Fig. 1.

### Generating domains

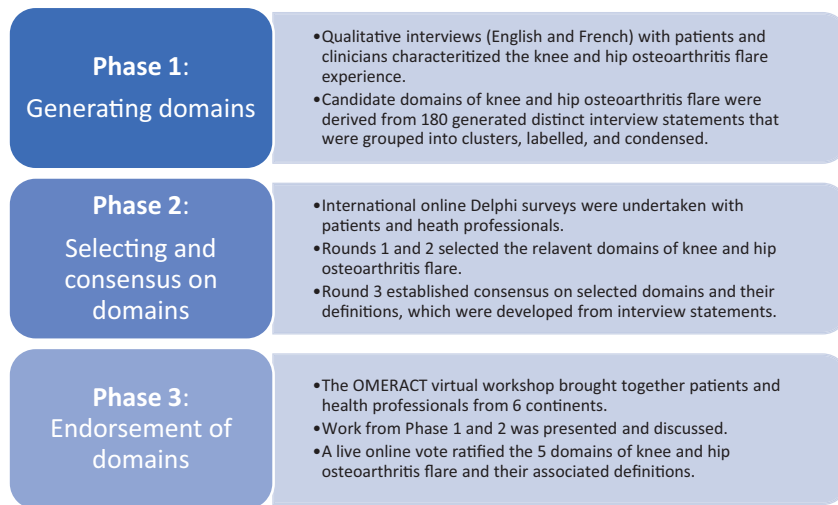
Our initial work generating and selecting the KHOA flare domains followed a bottom-up approach and has been previously reported [6]. In brief, in 2017, unstructured interviews were first completed in

persons with KHOA, with variation in recruitment across joint involvement, sex and age. Through content analysis, two senior health psychologists identified main themes related to OA flare, which informed the development of an interview guide for subsequent interviews. Semi-structured one-on-one interviews (face-to-face and telephone) were conducted in two languages (English and French) in Australia and France to understand the experience of KHOA flare. Participants included persons with KHOA recruited from investigator's practices or research cohorts, and clinicians (nurses, physical therapists, rheumatologists, general practitioners, orthopedic surgeons) from among active OARSI members, OMERACT Working Group members and colleagues. Interview transcripts were organized using NVivo software, and analyzed in parallel in both countries/languages. French statements were translated into English, as well as English into French, to generate a complete list of statements in the two languages that characterized KHOA flare. These were subsequently grouped into clusters. The dual-language approach endeavored to capture the same intended content and meaning across both languages, limiting idioms and colloquialisms, and facilitating future translation in other languages and enhancing generalizability [9]. The Working Group critically analyzed the clusters and descriptively labelled the clusters as proposed domains.

### Selecting domains: Delphi round 1 and 2

Two rounds of online Delphi surveys were conducted in 2018 among patients and HPs. Patients were recruited from Study of Risk Factors for Pain Exacerbation in Osteoarthritis of the Knee [10], and from a network of university hospital rheumatology centers in France. HPs included both clinicians and researchers/scientists recruited from OARSI membership and investigators' networks. Agreement was set at 70% in both patient and HPs stakeholder groups, in accordance with the OMERACT handbook [11].

Definitions of each domain, in English and French, were created using the statements characterizing KHOA flare from the initial qualitative data. This built on the definition of OA flare that was created at the OMERACT 2018 meeting using the same framework.



**Fig. 1.** Summary of the research process.

### *Consensus on domains and definitions: Delphi round 3*

A third round of online Delphi survey was completed in January 2020 to achieve agreement on the proposed domains of KHOA flare and their associated definitions. Patients and HPs were recruited from OARSI membership, and investigators' practices and networks. Agreement threshold was again set at 70% in both patient and HPs stakeholder groups. Free-response comments from patients and HPs were used to refine the definitions.

### *Endorsement of domains and definitions: OMERACT virtual workshop and vote*

Endorsement of domains was sought at two identical OMERACT Flares in OA workshops, held virtually due to the COVID-19 pandemic, June 30, 2020. These workshops were held within 24 h to accommodate different time zones and in order to enhance global stakeholder representation. Participants in the virtual workshops included patients, clinicians, researchers, and methodologists. Participants were asked to review provided online materials prior to the workshop to become familiar with the methods and results of the qualitative and Delphi survey phases of research. An animated video that summarized the group's work in generating, selecting and agreeing on the domains and definitions was made available online to be reviewed prior to the voting workshop [12]. An online recorded plenary presentation, in both languages, provided a more detailed report of the methods and results. Ahead of the workshop, participants were encouraged to interact with working group members regarding these materials, and the work completed to develop the domains, using an online discussion board.

During the 90-min virtual workshops, participants were presented with a brief summary of the work to date and then allocated to small breakout groups (nine groups in the first session, seven groups in the second session) with no more than 13 participants in each group. Patients and HPs were distributed equally between breakout groups, and each breakout group included an experienced facilitator and a content expert. Simultaneously in the small groups, over 30 min, participants were asked to consider the domains and definitions of OA flare. Designated breakout group reporters shared feedback from these discussions with the larger group. This was followed by a live vote on the domains and their definitions using a smart-phone based application guided by a moderator. Voting results from both workshop sessions were combined.

Following this, Working Group members incorporated feedback from the workshop to subtly revise the definitions of the domains for clarity while retaining their meaning.

### *Patient and public involvement*

Patients have been involved in all phases of this work and will play a key role in disseminating the final domains [13]. Two members of the Working Group are patient research partners (TB and SMC) and were involved in all phases of the domain development. During the online virtual workshops, both TB and SMC served as content experts, and SMC co-presented the plenary presentation. In addition, the virtual workshops included 27 stakeholders who identified as patients who participated and voted.

### *Ethics and consent*

This research was approved by the National Institutional Review Board in France (CNIL DR.–2015–134) and by the Human Research Ethics Committee at the University of Sydney, Australia. All patients and health professionals gave informed consent to participate in the research. The study is registered at [clinicaltrials.gov](https://clinicaltrials.gov) NCT02892058.

## **Results**

### *Generating domains*

Unstructured interviews were completed with 12 persons with KHOA. Semi-structured interviews gathered data from 29 patients and 16 HPs resulting in 180 statements characterizing KHOA flare. Statements were grouped into 9 clusters that were given descriptive labels. A full statement list and clustering scheme has been published in Guillemain et al. [6].

### *Selecting domains: Delphi rounds 1 and 2*

Participants in the first Delphi round included 91 patients and 165 HPs, and in the second Delphi round 50 patients and 116 HPs. Patients came from Canada, France and Australia; HPs were from 17 countries on four continents.

Nine domains were proposed in the initial two Delphi survey rounds. After two Delphi rounds, patients agreed ( $\geq 70\%$  endorsement) to keep seven domains (*Pain, Swelling, Stiffness, Psychological aspects, Triggers, Consequence of Symptoms and Protective factors*) and

to reject two others (*Buckling* and *Other symptoms*). In contrast, after two Delphi rounds, HP agreed ( $\geq 70\%$  endorsement) to keep six domains (*Pain*, *Swelling*, *Stiffness*, *Triggers*, *Consequence of symptoms* and *Protective factors*) of the seven endorsed by patients, and reject the same two (*Buckling* and *Other symptoms*). Among HPs, agreement to keep *Psychological aspects* was 67.2% and did not meet the 70% threshold. Given the endorsement by patients (72%) this was retained as a domain.

The Working Group merged two domains endorsed by both patients and HPs (*Consequence of symptoms* and *Protective factors*) into one domain called *Impact of symptoms* due to an overlap in content. One domain, *Triggers*, was removed by consensus of the Working Group as it was felt to reflect a cause and not a characteristic of flare. This resulted in five proposed domains of OA flare: *Pain during flares*, *Swelling during flares*, *Stiffness during flares*, *Psychological aspects during flares*, and *Impact of symptoms*.

### Consensus on domains and definitions: Delphi round 3

Participants in the third Delphi round included 38 patients and 89 HPs for both English and French languages across 3 continents. Both patient and HPs participants agreed to keep each of the five domains and their accompanying definitions with  $>70\%$  endorsement (Table 1).

### Endorsement of domains and definitions: OMERACT virtual workshop and vote

At the OMERACT 2020 virtual Flares in OA workshop, 27 patients and 106 HPs participated and voted. Registered participants were from 25 countries/six continents (North America, South America, Europe, Africa, Asia, Australia). Prior to the workshop, online discussion board threads between participants and Working Group members discussed reasons for the grouping of Hip and Knee OA together (as per the KHOA core domain set [5]), the definition of OA flare (as reported in Guillemin et al. [6]), and if all domains were required to be fulfilled for KHOA to be present (no, each patient will have a different and unique experience). During the workshop, several breakout groups reported that an explicit mention of fatigue and sleep was missing from the definition of *Impact of symptoms*, and some groups wished clarification that symptoms during flare were a distinct change from the pre-flare state.

In the vote, the proposed domains were ratified with 100% endorsement (27/27) among patients and 98% endorsement (104/106) among HPs. The ratified English domains of KHOA flare and their final definitions are shown in Table 2. The French language domains and definitions are presented in Table 3.

## Discussion

We report the OMERACT-endorsed domains of flare in KHOA, developed using OMERACT methodology and in collaboration with important internationally represented stakeholder groups, including patients with OA, clinicians involved in care of patients with OA,

methodologists, and OA researchers. These domains will be crucial to develop instruments to measure KHOA flare in research studies where flare is an outcome of interest, and to gather evidence on the validity of existing instruments. This work builds from the updated OMERACT-OARSI core domain set for clinical trials of persons with KHOA that identified KHOA flare in the research agenda[5].

The domains of KHOA flare represent relevant elements that capture the multidimensional construct of flare, distinct from a patient's baseline non-flare state. For instance, while *Pain* is included in the OARSI/OMERACT KHOA core domain set as mandatory in all trials[5], the OA flare domain of *Pain during flares* is a transient increase in pain from the baseline non-flare state that can accompany other aspects of the construct of flare. Similarly, while *Psychological impact* is an "important but optional domain" in the KHOA core set, *Psychological factors during flare* reflects a change that may occur during flare as part of the flare experience. This nuance is reflected in the definition of KHOA flare as: "it is a transient state, different from the usual state of the condition, with a duration of a few days, characterized by onset, worsening of pain, swelling, stiffness, impact on sleep, activity, functioning, and psychological aspects that can resolve spontaneously or lead to a need to adjust therapy"[6]. While the domains of KHOA flare uniquely characterize the KHOA flare experience, as expected, there are similarities to the endorsed domains of flare in rheumatoid arthritis [14, 15] that also reflect a multidimensional construct beyond an increase in pain alone.

To our knowledge, OMERACT participants have for the first time endorsed corresponding definitions alongside each domain that will be used to develop a composite instrument, and accomplished this all virtually. The working group feels this early presentation of definitions to the scientific community will enable the translation of these resolutions into practice. From the workshop feedback, we heard that participants could better appreciate the scope of the domains by having the definitions alongside. These definitions were strengthened by valuable feedback from both the Delphi survey participants in the lead-up to the workshop and from the OMERACT workshop participants, to clarify and strengthen their wording while retaining the meaning and keeping true to the original 180 items identified by our in-depth qualitative work.

This work has many strengths. The broad stakeholder input including patients with lived experience, methodologists, OA researchers, and clinicians who treat patients with KHOA, such as physical therapists, general practitioners, rheumatologists and orthopedic surgeons, provides important and multifaceted perspectives. The development and consensus in two languages, as well as the novel virtual workshop format that allowed a more geographically diverse representation of participants than would be possible at an in-person meeting, both enhance generalizability.

There are also some limitations to this work. While the proportion of patient participation was the strongest yet for an OMERACT-endorsed domain set, it did fall short of the 50% representation we were aiming for. It remains unclear what is the optimal threshold for balance of stakeholders. We did not have participation of regulators, or other stakeholder groups such as caregivers/essential care partners or individuals from the wellness sector such as fitness instructors.

**Table 1**

Results of the third Delphi round that sought consensus on the domains of knee and hip OA flare and their definitions.

Domain	Delphi for consensus on domains of Flare in knee/hip OA (% agreement)		
	Patients (n = 38)	Health professionals (n = 89)	All (n = 127)
Pain during flares	89.5	98.9	96.1
Swelling during flares	92.1	95.5	94.5
Stiffness during flares	97.4	94.4	95.3
Psychological aspects during flares	89.5	84.3	85.8
Impact of symptoms	94.7	96.6	96.1



**Table 2**  
Ratified domains and definitions of knee/hip OA Flare.

Domain	Definition
Pain during flares	A distinct change in pain, that is more severe and lasts longer, that is particularly heightened with physical activity and persists with rest.
Swelling during flares	A new increase in size or feeling of fullness of the joint.
Stiffness during flares	Increased or prolonged stiffness of the joint that does not resolve with movement.
Psychological aspects during flares	Alterations in mood, including depressive symptoms, greater anxiety, greater irritability, and/or low morale that are consequences of the symptoms during flare.
Impact of symptoms	A change in the ability to perform daily activities, requiring new adaptation and strategies due to the increase in pain, swelling, stiffness, fatigue and sleep disturbance related to the flare.

**Table 3**  
The French domains and definitions of knee and hip OA flare.

Domain	Definition
Douleur dans la poussée	Une douleur différente de d'habitude, plus grande et plus longue, particulièrement augmentée par l'activité physique et persistante au repos.
Gonflement dans la poussée	Un changement inusuel de volume ou une sensation de plénitude de l'articulation.
Raideur dans la poussée	Raideur prolongée ou augmentée de l'articulation, qui ne cède pas à la mobilisation
Aspects psychologiques dans la poussée	Altérations de l'humeur due aux symptômes de la poussée, y compris des symptômes de dépression, d'une plus grande anxiété, d'une plus grande irritabilité, et/ou une baisse de moral.
Impact des symptômes	Un changement dans la capacité à effectuer les activités de la vie quotidienne, conduisant à des adaptations et à l'utilisation de nouvelles stratégies en raison d'une augmentation de la douleur, du gonflement, de la fatigue et de troubles du sommeil liés à la poussée.

Despite the virtual format, some regions were underrepresented, particularly South America, Africa and Asia.

In conclusion, following OMERACT methodology and with broad stakeholder input, we have developed the domains of KHOA flare, with accompanying definitions. These domains represent the important aspects of KHOA flare that will inform the development of an instrument and further validation studies to measure KHOA flare in research studies where flare is an outcome of interest.

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**Lauren K. King:** Conceptualization, Methodology, Investigation, Writing - original draft. **Jonathan Epstein:** Conceptualization, Methodology, Investigation, Writing - review editing. **Marita Cross:** Conceptualization, Methodology, Investigation, Writing - review editing. **Marie Buzzi:** Methodology. **Thomas Buttell:** Conceptualization, Investigation, Writing - review editing. **Sam Michel Cembalo:** Conceptualization, Investigation. **Elisabeth Spitz:** Conceptualization, Methodology, Investigation. **Cameron L. Adams:** Investigation, Writing - review editing. **Adewale Adebajo:** Investigation, Writing -

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#### Acknowledgment

The authors wish to thank participants from all phases of this project, and the delegates who attended the virtual workshop. We thank the OMERACT executive for their guidance, and Melanie Beguinet and Camille Alleyrat who managed the Delphi surveys.

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