# Feasibility and Domain Validation of Rheumatoid Arthritis (RA) Flare Core Domain Set: Report of the OMERACT 2014 RA Flare Group Plenary

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***ABSTRACT.*** ***Objective.*** The Outcome Measures in Rheumatology (OMERACT) Rheumatoid Arthritis (RA) Flare Group was established to develop an approach to identify and measure RA flares. An overview of our OMERACT 2014 plenary is provided.

***Methods.*** Feasibility and validity of flare domains endorsed at OMERACT 11 (2012) were described based on initial data from 3 international studies collected using a common set of questions specific to RA flare. Mean flare frequency, severity, and duration data were presented, and domain scores were compared by flare status to examine known-groups validity. Breakout groups provided input for stiffness, self-management, contextual factors, and measurement considerations.

***Results.*** Flare data from 501 patients in an observational study indicated 39% were in flare, with mean (SD) severity of 6.0 (2.6) and 55% lasting > 14 days. Pain, physical function, fatigue, participation, and stiffness scores averaged ≥ 2 times higher (2 of 11 points) in flaring individuals. Correlations between flare domains and corresponding legacy instruments were obtained: r = 0.46 to 0.93. A combined definition (patient report of flare and 28-joint Disease Activity Score increase) was evaluated in 2 other trials, with similar results. Breakout groups debated specific measurement issues.

***Conclusion.*** These data contribute initial evidence of feasibility and content validation of the OMERACT RA Flare Core Domain Set. Our research agenda for OMERACT 2016 includes establishing duration/intensity criteria and developing criteria to identify RA flares using existing disease activity measures. Ongoing work will also address discordance between patient and physician ratings, facilitate application of flare criteria to clinical care, elucidate the role of self-management, and finalize recommendations for RA flare measurement. (First Release Feb 15 2015; J Rheumatol 2015;42:2185–9; doi:10.3899/ jrheum.141169)

*Key Indexing Terms:*
FLARE DISEASE EXACERBATION RHEUMATOID ARTHRITIS OMERACT

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Formalized methods to identify and characterize flares in rheumatoid arthritis (RA) across settings are much needed[1,2,3,4,5]. Low disease activity and remission are the recommended targets of treatment[6,7], and once achieved, it may be possible to taper therapies. However, a limitation of randomized clinical trials (RCT) and longitudinal observational studies (LOS), especially those reporting on treatment tapering/withdrawal, has been the lack of a validated endpoint to identify the return of significant disease activity (i.e., flare)[8]. The OMERACT RA flare group was established to address gaps in RA flare assessment. Since inception, an international steering committee of researchers and patient research partners have worked together to guide a larger group of RA researchers, clinicians, and patients with ongoing bidirectional input.

We defined clinically relevant inflammatory RA flares as reflecting a cluster of symptoms, signs, and effects of sufficient intensity and duration to require consideration of (re)initiation, change, or increase in therapy[1,2,5]. We began by conducting 14 focus groups across 5 countries with people with RA to identify experiences during a flare[9]. A conceptual framework was developed to identify essential symptoms and effects that represented disease flares, including their use of self-management strategies. Parallel and combined modified Delphi exercises were conducted with patients, healthcare providers (HCP), and researchers to gain consensus on candidate domains for a prototype measurement model[10]. Of note, researchers in additional settings independently identified similar flare domains[11,12], patient assessments of RA disease activity, and preferred treatment outcomes[13,14].

Results established a candidate RA flare core domain set, which was endorsed by attendees at the OMERACT 11 meeting at Pinehurst, North Carolina, USA, in 2012[4]. The RA flare core domain set included the American College of Rheumatology core set for RA[15], with fatigue, stiffness, participation, and self-management added. Our research agenda at OMERACT 11 was to: (1) identify existing instruments and/or develop new items if needed to assess each domain; and (2) gather preliminary evidence of content validation[16,17]. We developed a data collection tool to gather information about RA flare episodes at the time of clinical assessments in LOS and RCT. The questions to assess patient-reported flare and the OMERACT flare domains were rigorously translated (i.e., forward and back translation with adjudication and cognitive interviews)[18] from English into 13 languages. The questions comprised 3 sections: Section 1 asked patients to rate changes in their RA since the last visit (7-point Likert scale: much worse to much better), and whether respondents believed they were currently experiencing a flare (Y/N); if yes, respondents were asked to rate the severity of flare [11-point numerical rating scale (NRS)] in the past week, its duration (days), and indicate use of self-management strategies (from a list provided). Section 2 asked for ratings of 6 domains (pain, physical function, fatigue, stiffness, participation, and coping) using an 11-point NRS. Section 3 asked respondents to indicate swollen and tender joints on a homunculus (counts of swollen joints and tender joints).

Here is an overview of results presented at an OMERACT 2014 plenary to validate flare domains, summarize breakout group discussions, identify remaining gaps, and provide an updated research agenda to finalize recommendations for flare assessment.

## METHODS

### Overview of Plenary Session

Prior to the plenary, a briefing session was held for patients to become familiar with our prior work and current goals to facilitate their participation during the conference. During the plenary, we summarized evidence from flare data from 2 LOS and 1 RCT supporting feasibility and content validity of flare domains. One-hour breakout groups allowed presentation of additional data and structured discussions to inform the research agenda. Reports from the breakout groups were then provided to the larger OMERACT group.

## RESULTS

### Preliminary Results from LOS and RCT

The Canadian Early Arthritis Cohort (CATCH) is a LOS that captures extensive clinical information and patient-reported outcomes every 3 to 6 months from 19 sites across Canada[19]. Flare questions were completed by 501 patients at 2 consecutive visits. Of 39% who reported being in a flare at the visit, the mean (SD) flare severity was 6.0 (2.6), and 67% reported flares > 7 days and 55% > 14 days. Domain scores were compared by flare status (flare vs no flare) using 3 flare classification systems: (1) patient-reported flare; (2) MD-reported flare; and (3) a 28-joint Disease Activity Score (DAS28)-based definition[20]. Across all definitions, flare domain scores were, on average, at least twice as high among people classified as flaring versus those not flaring, with clinically meaningful and statistically significant differences between groups. Correlations between domain scores and legacy items/scales (Health Assessment Questionnaire; fatigue visual analog scale; Veterans Rand 12-item Health Survey; Worker Productivity and Activity Impairment Questionnaire–Rheumatoid Arthritis; RA Disease Activity Index; and Patient Global) measuring similar constructs showed moderate to high agreement for pain ($r \geq 0.87$), physical function ($r \geq 0.64$), fatigue ($r \geq 0.72$), participation ($r \geq 0.65$), and stiffness ($r \geq 0.46$) across flare definitions (Table 1). The most common self-management strategies endorsed included taking additional analgesics (51%), and reducing (49%) or avoiding (32%) activities, with 5% indicating increasing use of steroids.

A combined flare definition [patient report of flare and DAS28 increase (DAS scores < 3.2 at second visit required an increase of 1.2 units whereas DAS ≥ 3.2 at second visit required increase of 0.6)[21]] was also evaluated with initial data

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*Table 1.* Relationship between OMERACT rheumatoid arthritis (RA) flare core domains and legacy PRO measures or joint counts by flare status*.

| Domains | | All | Physician** | | Patient*** | | DAS28† | |
|---|---|---|---|---|---|---|---|---|
| | | | Yes | No | Yes | No | Yes | No |
| | Source | n = 501 | n = 148 | n = 253 | n = 124 | n = 377 | n = 49 | n = 264 |
| Pain | | | | | | | | |
| How much pain due to RA in past week? | HAQ | 0.91 | 0.87 | 0.91 | 0.87 | 0.88 | 0.83 | 0.90 |
| Today's level of pain today | RADAI | 0.84 | 0.81 | 0.81 | 0.83 | 0.79 | 0.80 | 0.85 |
| Pain past week | Pt Global | 0.93 | 0.89 | 0.92 | 0.87 | 0.90 | 0.91 | 0.90 |
| Joint area pain severity (0-48) | RADAI | 0.72 | 0.65 | 0.70 | 0.59 | 0.69 | 0.51 | 0.75 |
| Patient tender joint count (40) | Patient | 0.54 | 0.41 | 0.57 | 0.35 | 0.49 | 0.37 | 0.63 |
| MD tender joint count (28) | MD | 0.50 | 0.33 | 0.50 | 0.29 | 0.43 | 0.29 | 0.51 |
| Physical function | | | | | | | | |
| Disability score (0–3) | HAQ | 0.76 | 0.73 | 0.71 | 0.70 | 0.68 | 0.63 | 0.77 |
| Physical function | RAND–12 | -0.68 | -0.68 | -0.61 | -0.71 | -0.60 | -0.64 | -0.67 |
| Daily activities in past 7 days | WPAI | 0.82 | 0.80 | 0.78 | 0.80 | 0.80 | 0.75 | 0.81 |
| Fatigue | | | | | | | | |
| Vitality (Rand-12) | RAND-12 | –0.62 | –0.60 | –0.65 | –0.64 | –0.59 | –0.69 | –0.61 |
| Unusual fatigue/tiredness past week | Pt Global | 0.88 | 0.81 | 0.88 | 0.78 | 0.87 | 0.81 | 0.89 |
| Participation | | | | | | | | |
| Role — physical | RAND-12 | –0.72 | –0.65 | –0.71 | –0.69 | –0.66 | –0.70 | –0.67 |
| Social function | RAND-12 | –0.61 | –0.67 | –0.60 | –0.72 | –0.49 | –0.68 | –0.61 |
| Productivity while working | WPAI | 0.79 | 0.83 | 0.82 | 0.84 | 0.74 | 0.77 | 0.79 |
| RA affecting daily activities | WPAI | 0.82 | 0.78 | 0.80 | 0.76 | 0.79 | 0.79 | 0.81 |
| Stiffness | | | | | | | | |
| AM joint stiffness score | RADAI | 0.68 | 0.58 | 0.65 | 0.52 | 0.64 | 0.57 | 0.71 |

*Spearman correlation coefficients for second visit. **Physician endorsement of flare based on rating ≥ 0.5 cm on flare severity 100 mm VAS. ***Patient classification of flare based on Yes/No. †DAS scores < 3.2 at second visit required an increase of 1.2 units whereas DAS ≥ 3.2 at second visit required increase of 0.6. HAQ: Health Assessment Questionnaire; RADAI: Rheumatoid Arthritis Disease Activity Index; Pt. Global: Patient Global Assessment of Disease Activity; VR-12: Veteran Rand-12 Health Survey; WPAI: Work Productivity and Activity Impairment-Rheumatoid Arthritis; PRO: patient-reported outcome; DAS28: 28-joint Disease Activity Score; RAND-12: Veterans Rand 12-item Health Survey.

from the BIODAM-RA Study, a 10-country LOS to validate biomarkers that predict joint damage and DRESS RCT (Dose Reduction Strategy of Subcutaneous Tumor Necrosis Factor Inhibitors in RA)[21]. The overall flare rate was 14%; 56% had persisted > 7 days. Persons in flare scored significantly higher on all domains, ranging from 2.6 for stiffness to 3.6 for pain compared with 0.1 and 0.2 for stiffness and pain, respectively, in those not in flare. Patient-reported joint counts were also significantly higher in flare versus no flare (tender joint count 6.0 vs 0.1, swollen joint count 4.3 vs 0.1; $p < 0.001$). In regression analyses, group differences persisted after adjustment for sex, age, disease duration, flare severity, and study type. Together, these data contribute new evidence of the feasibility of assessing flares with clinical and patient-reported data, and provide initial evidence of content validation of the RA flare core domain set.

**Breakout Groups**

OMERACT attendees were randomly assigned to 1 of 6 breakout groups; anyone could elect to attend a seventh group focused on methodological considerations. At the end of the breakout sessions, reports outlining themes and recommendations that emerged for flare assessment from each group were provided to all attendees.

**Stiffness**

Although stiffness was identified as a core RA flare domain, it remains unclear how to best assess stiffness. Results from focus groups with 20 participants (USA[22]) and 16 individual interviews (UK[23]) were presented. Findings suggested that people with RA described the experience of stiffness in terms of severity and effect throughout the day, rather than as the duration of morning symptoms.

The 36 participants broke into 2 smaller groups, and there was agreement that querying only morning stiffness duration may not adequately capture patients' experiences and does not address effect. There was agreement that it may be helpful to expand current conceptualizations of stiffness, and there was interest in creating a special interest group for stiffness across rheumatic diseases (see Orbai, *et al*[24]).

**Self-management**

Participants in 2 groups agreed that self-management (e.g., use of steroids, analgesics) can affect the intensity/duration of flare symptoms and effects. In 1 group (n = 16), most (13/15) viewed self-management as a core flare domain, while in the other (n = 7), opinions were divided about whether self-management was best conceptualized as a core domain or contextual factor. Participants noted no measures

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currently exist to query self-management strategies commonly used in RA. The groups felt that the self-management question we used did not sufficiently cover the range of self-management activities that patients with RA use, that it required a validated scoring strategy, and that it would need to detect practices beyond what the person usually does (e.g., taking additional analgesics, reducing/avoiding activities, etc.). While overlap between self-management and coping was recognized, it was concluded these represent currently ill-defined but different constructs and that further study was needed to assess self-management across rheumatic conditions.

### Contextual Factors

A requirement of the OMERACT Filter 2.0 is the identification of key contextual factors to include in outcome measurement models[25]. Two breakout groups (n = 10 and n = 8) identified and prioritized potential flare contextual factors in RCT and LOS.

Contextual factors are factors that are not the primary focus of the research, but may influence interpretation of the results[25]. A wide range of factors that could potentially affect outcomes were discussed, including factors specific for RA, comorbidity, the person, and the therapy. There was uncertainty about how to identify contextual factors, the extent to which they are applicable across settings, and whether they contribute unique information that is required to interpret flare assessment results. In the OMERACT Filter 2.0 report it is noted that a contextual factor can be declared "core" when it significantly modifies intervention outcomes; and self-management is cited as an example[25]. There was strong endorsement in these groups for a separate effort to address defining and measuring contextual factors in other conditions.

### Measurement Considerations in Evaluating Flares

Discussion in the measurement breakout, attended by 22 participants, centered around several themes. The current flare definition, which ties the identification of flare to specific actions (i.e., consideration of treatment change), is potentially problematic. The relative value of characterizing flare as an extension of disease activity (e.g., a change in the DAS28 vs as a separate construct) was also debated. There was agreement that it was important to determine whether flare conceptual models should be reflective (i.e., core domains serve as flare indicators) or formative (i.e., flare summarizes variation in core domains[17]; Figure 1). To evaluate evidence of unidimensionality (i.e., that flare might be represented using a single summative score of domains), additional analyses were recommended. Specific questions were voted on during the session. Most (17/22) agreed that both traditional (classical test theory) and modern measurement methods (e.g., item response theory, Rasch theory) should be considered when developing any new measure. Almost all (20/22) agreed that flare reflects a change in state that persists for a specific duration, but it was less clear how much worsening was required over how many days, and whether increases in disease activity should be evaluated relative to current levels and/or prior state.

There was consensus that agreement of flare status by both patients and HCP increased confidence that the person was experiencing an inflammatory flare. For clinicians, a binary classification system may be desirable (flare vs not in flare). There was also general agreement that over-diagnosis of flare could result in over-treatment and that the relative balance of specificity versus sensitivity may vary by setting (e.g., clinical care vs RCT). Finally, some voiced concern that development of a paper-based, separate flare assessment tool to be administered at each visit could be burdensome to patients and staff.

### Drawing Up the Research Agenda

Since OMERACT 10, the RA Flare Group has developed methods and assembled an international group of collaborators to collect flare data in ongoing LOS and RCT. We presented results from initial data collected that supports the feasibility and content validity of the RA flare core domain set and demonstrated the prevalence, symptoms, and effect of RA flares. Breakout group discussions noted potential research needs around assessing stiffness and self-management, and the need to clarify methods to evaluate contextual factors across settings. Opinions ranged on whether self-management is a core domain, contextual factor, or both.

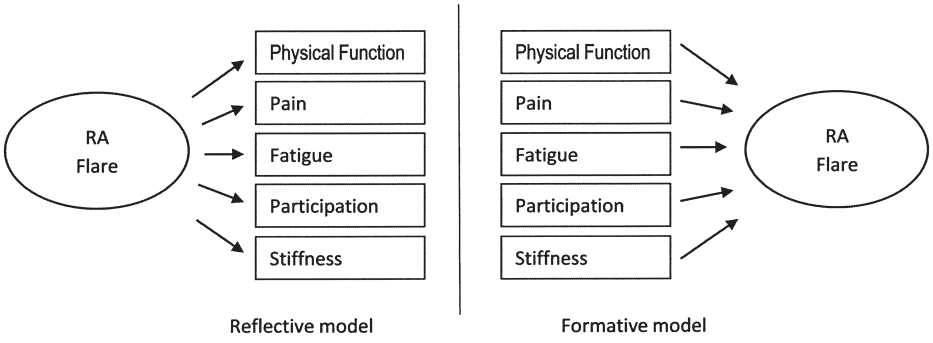


*Figure 1*. Rheumatoid arthritis (RA) flare represented as a reflective or formative model.

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The research agenda for OMERACT 2016 includes using flare data currently being collected in multiple international studies to identify: (1) appropriate anchors for flare assessment including agreement (patient/MD, patient/DAS criteria); (2) duration and intensity thresholds; and (3) factors associated with disagreement regarding flare status between patients and providers. Additional work is being conducted by our group to establish the incremental value of the additional RA flare domains over the RA core set in assessing flare, the need for new measures of selected domains (e.g., stiffness, participation, self-management), recommended cutpoints to assess flare using existing measures, and opportunities to integrate flare assessments into patient self-management and RA care.

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