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# Development of a Flare Instrument for Use in Psoriatic Disease: A Report from the 2015 GRAPPA Annual Meeting

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**ABSTRACT** (n = 244)

**Background**: The objective of this GRAPPA initiative is to develop a questionnaire to determine the presence of a flare of disease activity in psoriatic disease (PsD), for use in clinical care and research settings.

**Methods**: In 2014–2015, two online Delphi surveys of patients and physicians attempted to achieve consensus about items that might discriminate a flare of disease. In the first round, items were derived from previous qualitative studies with patients; in the second round, new items, suggested by both patients and physicians, were added. Survey results were discussed at the 2015 GRAPPA annual meeting, and 8 breakout groups discussed specific aspects of PsD flares.

**Results**: Survey participants were patients (n=103 and n=57 in rounds 1 and 2) and physicians (n=125 and n=81). Items for flare covered 6 domains (joints, skin, emotion, participation, fatigue, and unclassified). Patients agreed that 20 items were important (10 joints, 1 participation, 8 fatigue, 1 unclassified), and physicians agreed on 23 items (5 skin, 11 joints, 4 participation, 3 unclassified). Eight items were selected as important by both groups: 7 joint items and 1 unclassified.

Patients emphasized fatigue and physicians emphasized skin and participation. Breakout groups concluded that the components of a flare instrument should be derived from patients. A flare should be defined as a change in disease state requiring intervention.

**Conclusions**: The concept of flare in PsD covers articular, skin, emotional, participation, and fatigue domains. Further work is required to specify items that represent these domains.

## INTRODUCTION

Psoriatic arthritis (PsA) and psoriasis are chronic disabling conditions with common pathogenic mechanisms.(1) Together with associated comorbidities they form part of what is known as psoriatic disease (PsD). The core elements assessed in PsA clinical trials include peripheral joint activity, skin activity, patient's global assessment, pain, physical function, and health-related quality of life (HRQoL).(2) Items thought to be important in assessment but not part of the core set include enthesitis, dactylitis, nail and spinal disease, fatigue, physician global assessment, and radiology. The domains of impact vary between physician and patient perspectives; patients identify pain, fatigue, and skin symptoms as the top three.(3) Further development is ongoing of the core set of domains and the composite measures that include them.(4, 5)

As mentioned above, disease activity may not be sufficiently described using only the core set. Indeed, patients often describe a flare of their disease, which they describe as something that is experienced beyond just the physical symptoms of the disease. In a recent qualitative study, patients identified nine overarching themes pertaining to flare: physical symptoms, social withdrawal, psychological symptoms, fatigue, loss of normal function, triggers, management of pre-flare, management of flare, and timing.(6) Emotional and psychological items also appeared as important domains of impact in another study that used the patient perspective.(7)

No measures have been validated to assess disease flare in PsD. A systematic literature review in 2011 found only 5 articles relating to flare in PsA. Most studies analysed the inverse, or absence, of a disease target, such as remission or low disease activity.(7) Similar studies assessing the prevalence of flare after treatment tapering and withdrawal have identified the absence of low disease activity as the definition of flare.(8, 9)

The purpose of the current study is to develop an instrument that can be used to determine the presence of a flare of disease activity in PsD. The study builds on previous qualitative work to further refine a definition of flare primarily from the patients' point of view. In collaboration with the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA), surveys of both patients and physicians were undertaken and discussed at the GRAPPA annual meeting in July 2015.

## METHODS

Full ethical approval was obtained for this study (**NRES Committee Yorkshire & The Humber - Bradford Leeds: 12/YH/0041).**

The process to develop a flare questionnaire comprised several steps.

### 1. Initial list of discriminatory items that would be part of a flare instrument

These items were obtained from a qualitative interview study (6) in which 18 patients were interviewed about their experiences of flare. Transcripts were analysed and items coded into 9 overarching themes: physical symptoms, triggers, management of pre-flare, social withdrawal, fatigue, loss of normal function, psychological symptoms, timing, and management of flare. (6)

### 2. Delphi surveys

Items

The first survey was conducted on the internet using SurveyMonkey software (https://www.surveymonkey.com/) between September and December 2014. The purpose of the survey was to obtain consensus among patients as well as physicians on the important and discriminatory items that would be part of a flare instrument. The wording of items obtained in the patient interviews was retained. Respondents were asked to rate the ability of each item to identify a flare, and were asked to consider a recent change or increase in that item. The response options were a numerical rating scale with 9 points from 1 (not discriminating at all) to 9 (extremely discriminating). Respondents were also offered a “don’t know” option. Items were presented under 5 general headings: skin (13 items), joints (19 items), emotional (16 items), participation (13 items), fatigue (8 items), and unclassified (10 items). If 70% or more of respondents in one group graded the item as 6 or above then the item was deemed to be accepted by the respondents of that group as a discriminating item for flare. Similarly, if 70% graded the item as 5 or below, the item was regarded as not discriminating and removed. A free text field was available for comments and suggestions for items that were thought to be important but missing.

Using the results of the first survey, a second survey with a reduced item set was used for both physicians and patients. From the first survey, items were omitted that achieved consensus (either to remove, or to include) by the physicians. This enabled us to send only one further survey, rather than two different surveys (one to patients and one to physicians).

Further, the mean response score (appropriately for patients and physicians) from the first survey was included with each item, as a guide for respondents, who were encouraged to vote at the extremes of response. In addition, new items suggested in the free text field of the first survey were also included. The surveys were all in English and were identical for both physicians and patients.

Participants

The physician group comprised the membership of GRAPPA, a worldwide organisation with approximately 503 members having roughly one-third dermatologists and two-thirds rheumatologists. A small number of patients (the GRAPPA patient research partners) also responded in this cohort but the responses were transferred to the patients' survey results. The patient groups comprised members of the Psoriasis and Psoriatic Arthritis Alliance (PAPAA), an organisation in the United Kingdom (UK) with over 5000 members (www.papaa.org). Patients were invited to complete the survey online by a link available on the association website, as well as by mention in the society newsletter. Patients were also included from a second patient organisation, also based in the UK, which has a smaller membership of about 100 members (PSAZZ, psazzgroup.wix.com/psazz).

**3. Face-to-face discussion**

The results of the surveys were presented at the GRAPPA annual meeting in Stockholm, July 2015. Following plenary presentations, members (175 registrants, 10 patients, 108 physicians, 25 trainee physicians, and 32 industry partners) divided into 8 breakout groups of approximately 20 participants each. Each group included a GRAPPA patient research partner,(10) an even distribution of dermatologists and rheumatologists, a proportion of trainees, and a facilitator. Each group addressed a specific topic: symptom duration to define a flare; objective signs and change values defining a flare; final use of a flare questionnaire as a physician questionnaire or patient-reported-only questionnaire; and use in clinical practice or research of a flare questionnaire. Each group also specifically discussed a domain from the survey, the latter using the nominal group technique where each individual "silently" pre-ranked the items. The results of the discussions were presented in a final GRAPPA plenary session.

## RESULTS

### Survey

The demographics of the respondents to each survey are provided in **Table 1**.

One hundred three patients responded to the initial survey (57 to the second survey); 125 and 81 physicians responded to the first and second surveys. There were 79 items in the first survey, 53 in the second. The results of the surveys, in terms of items accepted or rejected, are given separately for patients and physicians in **Table 2**, and the individual item responses to the first and second round are given in the supplementary material (**Supplementary Tables 3–8**), where the items accepted and rejected are highlighted. Twelve new items were suggested by respondents to the first survey and two of these (joint swelling and night pain) were agreed as important by both patients and physicians in the second survey.

As a result of this exercise, a total of 20 items were agreed as important by patients (10 joints, 1 participation, 8 fatigue, 1 unclassified), and 23 items by physicians (5 skin, 11 joints, 4 participation, 3 unclassified). Eight of these items were accepted by both groups: 7 joint items and one unclassified:

1. A recent change in joint pain
2. A recent change in location of symptoms (i.e., sudden increase in pain or swelling in hands/feet)
3. A recent change in the number of tender and/or sore joints
4. A recent change in the number of aching joints
5. The presence or degree of pressure sensitive joints
6. A recent change/increase in the number of swollen joints
7. A recent change/increase in night pain
8. A recent change/increase in the number or combination of symptoms

## BREAKOUT GROUPS DISCUSSION

### Symptom duration

Flare can be defined as a change in disease state that necessitates a change in treatment or as a marked worsening of ability to continue with activities of daily living. Flare was

regarded as short-lived and acute as distinguished from worsening of disease, which is slower and longer-lived. A flare would take the form of hours to days of worsening of joints and days to weeks of worsening of skin.

**Objective signs and change values**

A mapping exercise was suggested so that any flare instrument would be related to objective signs and change values of both other patient-reported instruments, such as Psoriatic Arthritis Quality of Life instrument (PsAQOL),(11) Psoriatic Arthritis Impact of Disease instrument (PsAID),(3) Short Form 36 (SF36), Health Assessment Questionnaire (HAQ),(12) and Routine Assessment of Patient Index Data 3 (RAPID 3),(13) as well as to objective measures of disease activity such as the Psoriasis Area and Severity Index (PASI) (14) or Body Surface Area (BSA) for skin; joint counts; and measures of axial disease, enthesitis, and dactylitis. Groups also considered the relationship of the flare instrument to the global Visual Analogue Scale (VAS) (both patient and physician) scores.

**Physician or patient reported**

It was agreed that a flare instrument should be a patient-reported outcome developed in collaboration with physicians.

**Use in clinical practice or research**

In general it was thought that instruments for both clinical practice and research should be available. However, the use of an instrument as a research or clinical tool would alter the cutoff for sensitivity or specificity of the instrument. No clear consensus was achieved on the duration of symptoms, but a flare could be defined as a change in disease state requiring intervention. A flare instrument could be mapped to many objective signs and change values. No decision was confirmed during this meeting about whether a flare instrument should be exclusively for clinical or research use.

**Domains and items**

A number of groups chose five key questions to measure a domain. Generally, the groups thought too many joint items were included in the survey, and many of the questions were similar; however, with regard to joint aspects of flare, the five key questions were joint pain, swollen joints, morning stiffness, location, and number of joints.

Group members identified the need for further work on skin symptomatology, with some emphasis also on widening the survey to patients in other countries and other cultures. They

emphasized a few key points related to skin symptoms, namely area of skin involvement, itching of skin, and redness/heat of skin. The groups decided that participation could be covered by 5 key questions: ability to do normal activities, motivation and concentration, quality of life, ability to move easily, and relationships. They decided that emotion is subject to cultural differences, making it hard to generalise internationally.

Fatigue was discussed as the most important symptom of flare as it serves both as a marker of a prodrome (to meaningful symptom change) and as a lag phase after the flare has been treated. Groups confirmed that flare was distinguishable from other causes of fatigue (such as jet lag and post-operative fatigue), and also agreed that fatigue was culturally variable. Furthermore, it was suggested that fatigue should be differentiated from other causes of symptoms, such as fibromyalgia; however, if this means physicians have to rule out fibromyalgia, it may be short-sighted as fatigue is a complaint of many members of the PRP group and other PsA patients.

From the 12 unclassified items in the original Delphi, those ranked outside the top 3 by members of the group were excluded, leaving 9 items for further review. Among those items were: combination/number of symptoms, duration of symptoms, flu-like feeling, and need to self-medicate.

## DISCUSSION

In this study, we report further work towards the development of a patient-reported instrument to measure flare in psoriatic disease. The results show a clear discrepancy between patients and physicians in items deemed discriminatory for a flare of the disease, with patients placing more emphasis on fatigue items and physicians more emphasis on participation. Both groups agreed on 7 joint items and 1 skin item. Discussions in small groups further refined what a flare instrument should be but more work is needed on the individual items. It is important to keep any instrument feasible and suitable for use in the clinic and research settings.

What can be said about a flare in PsD from the point of view of a patient? It is clear that it encompasses not only physical items, such as the joints and the skin, but also items such as emotion, fatigue, and participation. Indeed, the temporal relationship of these items to the flare may vary—fatigue may precede the worsening of joints and skin, and fatigue and participation may take longer to resolve after the flare is controlled. It is also important to note that the decision to develop a patient-reported measure of flare will exclude objective measures of

disease such as joint counts and skin assessments. However, the validation phase of the measure will include mapping onto these objective signs, as well as onto other patient-reported outcomes.

A challenge in developing a flare instrument will be the heterogeneity of the disease. For example, a patient may experience a flare of the skin but not the musculoskeletal manifestations. Alternatively, the patient may have an isolated flare of enthesitis, such as pain in the heel, or axial pain. The ability of a flare instrument to capture this adequately will require careful study. There is also the question of degrees of flare severity. A patient may appropriately self-manage a mild flare, but need a change in medication for a severe one.

An alternative challenge, and a limitation of the current study, is the divergence between patients and physicians in the selection of items that might be discriminative for a flare. In the first survey, discordance was demonstrated; if we had sent two separate surveys for the second round, we would have only further increased these disparate views. Although this disparity was not resolved ideally, we chose to send the same items to both patients and physicians for the second survey, which helped provide some degree of consensus, albeit a minimal one.

A further limitation of the current study is whether the patient population surveyed is representative. The international membership of GRAPPA ensured a global perspective for physician input. However, as cultural and ethnic concerns could possibly influence responses, it is important to ensure that patients from different countries are evaluated as the work proceeds.

One of the drivers to develop a flare instrument has been the success of biological therapies in PsD. As patients enter low disease activity, the possibility of stopping the drug appears, as early remission may have caused a change in disease status. Of the three main treatment withdrawal studies to date, the main outcome has been an absence of the remission (or low disease activity) state, rather than a true measure of flare of the disease.(8, 9, 15) An instrument to measure flare will be of use in these situations, as well as measuring disease status in the clinic. Ultimately, the relationship between patient-reported flare and composite measures of disease activity will be of interest, although existing composite measures do include patient-reported outcomes. Thus components of a flare instrument may eventually be incorporated in such instruments.(5)

The development of a flare instrument for PsA should be considered alongside a similar effort in rheumatoid arthritis (RA), which has been underway for more than 4 years. A qualitative study in self-management strategies of RA patients showed that flare is variably

characterised by patients as stiffness, swelling, and pain.(16) This RA study was primarily conducted to explore some variations with ethnicity on attributing cause of flare and how to manage a flare, providing further useful information from the patient's perspective on ethnic variants and variability.(16) Disease flare definition may also depend on a patient's duration of disease,(17) and patients have reflected that experience comes with longer disease duration.(18) Patients also describe how the relative importance of pain and mobility change over time, with pain being a consistent problem in flare throughout disease, and changes in mobility coming later.(17) In parallel, a French group has developed a self-administered questionnaire to identify past or present rheumatoid flare, the FLARE questionnaire.(19) Much work from RA can be adapted for use in PsA because of similarities in the articular disease; however, it is necessary to address further domains of the disease as outlined above and with reference to the inner, outer, and peripheral circles of the Outcome Measures in Rheumatology (OMERACT) core set for PsA.(2)

In conclusion, the concept of flare in PsD covers articular, skin, fatigue, emotional, and participation domains. The search is ongoing for specific items to represent these domains and will include further consensus exercises to rank items in order of importance. Existing databases also must be explored to validate any proposed measure.

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**Table 1: Demographics of the respondents to the surveys**

| | Physicians | | Patients | |
|---|---|---|---|---|
| | **First survey** | **Second survey** | **First survey** | **Second survey** |
| N | 125 | 81 | 103 | 57 |
| Age, mean years | 49 | 49 | 55* | 57* |
| Gender: N (%) | | | | |
| Male | 86 (69) | 59 (73) | 26 (25) | 11 (19) |
| Female | 39 (31) | 22 (27) | 77 (75) | 46 (81) |
| Speciality: N (%) | | | N/A | N/A |
| Rheumatology | 96 (77) | 62 (77) | | |
| Dermatology | 29 (23) | 19 (23) | | |
| Patients: N (%) | N/A | N/A | | |
| Psoriasis | | | 8 (8) | 2 (3) |
| Psoriatic arthritis | | | 95 (92) | 55 (97) |

N/A = not applicable

* Approximate mean age; patients were only asked to designate an age range.

**Table 2: Number of items accepted and rejected, by domain and respondent, in two rounds of survey.**

| Survey 1 | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | **Patients** | | **Physicians** | | **Agreement between patients and physicians** | |
| | **Number of items** | **Accept*** | **Reject#** | **Accept*** | **Reject#** | **Accept** | **Reject** |
| Skin | 13 | 0 | 6 | 0 | 2 | 0 | 2 |
| Joints | 19 | 5 | 1 | 8 | 2 | 4 | 1 |
| Emotional | 16 | 0 | 4 | 0 | 13 | 0 | 3 |
| Participation | 13 | 0 | 1 | 4 | 5 | 0 | 1 |
| Fatigue | 8 | 7 | 0 | 0 | 0 | 0 | 0 |
| Miscellaneous | 10 | 0 | 3 | 1 | 3 | 0 | 1 |
| TOTAL | 79 | | | | | | |
| **Survey 2** | | | | | | | |
| | **Number of items from Survey 1 (plus new items)** | **Patients** | | **Physicians** | | **Agreement between patients and physicians** | |
| | | **Accept** | **Reject** | **Accept** | **Reject** | **Accept** | **Reject** |
| Skin | 11 (+ 5) | 0 | 4 | 5 | 6 | 0 | 4 |
| Joints | 9 (+ 4) | 7 | 0 | 3 | 0 | 3 | 0 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Emotional | 3 (+ 2) | 0 | 2 | 0 | 5 | 0 | 2 |
| Participation | 4 (+ 1) | 1 | 0 | 0 | 0 | 0 | 0 |
| Fatigue | 8 | 8 | 0 | 0 | 1 | 0 | 0 |
| Miscellaneous | 6 | 1 | 0 | 2 | 0 | 1 | 0 |
| TOTAL (includes new items) | 53 | | | | | | |

* based on ≥ 70% recording 6 or more

\# based on ≥ 70% recording 5 or less