EXTENDED REPORT

A tool to identify recent or present rheumatoid arthritis flare from both patient and physician perspectives: The 'FLARE' instrument

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ABSTRACT

Introduction There is a lack of consensus about the definition of flare of rheumatoid arthritis (RA) and a measurement tool.

Objectives To develop a self-administered tool integrating the perspectives of the patient and the rheumatologist, enabling the detection of present or recent-past RA flare.

Methods The patient perspective was explored by semistructured individual interviews of patients with RA. Two health psychologists conducted a content analysis to extract items best describing flare from the interviews. The physician's perspective was explored through a Delphi exercise conducted among a panel of 13 rheumatologists. A comprehensive list of items produced in the first round was reduced in a four-round Delphi process to select items cited by at least 75% of the respondents. The identified elements were assembled in domains—each converted into a statement—to constitute the final self-administered Flare Assessment in Rheumatoid Arthritis (FLARE) questionnaire.

Results The content of 99 patient interviews was analysed, and 10 domains were identified: joint swelling or pain, night pain, fatigue and different emotional consequences, as well as analgesic intake. The Delphi process for physicians identified eight domains related to objective RA symptoms and drug intake, of which only four were common to domains for patients. Finally, 13 domains were retained in the FLARE questionnaire, formulated as 13 statements with a Likert-scale response modality of six answers ranging from 'absolutely true' to 'completely untrue'.

Conclusion Two different methods, for patient and physician perspectives, were used to develop the FLARE self-administered questionnaire, which can identify past or present RA flare.

INTRODUCTION

Although the question of a consensual definition of rheumatoid arthritis (RA) flare has been raised previously,^{1–4} clinicians still lack a consensual definition for it, from either a conceptual or practical point of view.^{1–4} This lack of consensus is due in part to the ambiguity of the concept because of two possible approaches to the definition.

The first approach may represent an ongoing worsening in RA activity of sufficient duration to prompt a change in RA treatment. This approach has been preferred by the Outcome Measures in Rheumatology (OMERACT) Flare group, which sought mainly to describe clinically relevant worsening, first in randomised controlled trials (RCTs) incorporating the patient's perspective, to improve the ability to capture loss of efficacy as early as possible in RCTs and longitudinal observational and post-marketing studies,⁵ and ultimately in clinical practice.⁶ In a preliminary definition, flare was accordingly defined as 'a cluster of symptoms of sufficient duration and intensity that cannot be self-managed by the patient and require initiation, change or increase in therapy'.^{2,5,7} In this approach, flare is the opposite of improvement, keeping in mind that the intensity of change is not symmetrical between the two notions.

In the context of RCTs, visits are already scheduled and separated by quite short intervals, allowing adaptation of the treatment as soon as a significant 'flare' is prospectively detected. This definition of flare does not yet consider the possibility of transient exacerbation of disease activity with spontaneous return to baseline disease activity.

The second approach encompasses any disease exacerbation, either transient (ie, spontaneously regressive) or long lasting. Such a definition would be more suitable for all settings, either in clinical research or daily practice, for identifying present flare or exacerbation of RA activity that has occurred between two visits to the physician. Transient flares definitely occur during RA, and may have significant impact on disease outcome. Welsing *et al* showed that brief and marked fluctuations in disease activity in patients with apparently stable RA are directly related to radiographic evidence of disease progression, which suggests that, at the individual level, transient fluctuations can also induce variation in structural damage.⁸ This evidence may explain structural damage progression in patients with apparent remission at successive medical visits. Because fluctuations in disease activity are common in chronic inflammatory rheumatism,⁹ there is definitely an unmet

need to identify such transient flares because they would be predictive of future worse outcome and would justify treatment adaptation even in patients in stable remission at the time of the consultation.

Defining RA flare raises another complex issue related to the difference in perception or concept of flare between patients and health professionals. Physicians may focus more on objective signs, such as the clinical features observed during the medical visit, but fail to notice patient-reported events that occurred before the consultation. Patients may have a different concept, depending first on what they experience in daily life as a consequence of the disease and its activity. For instance, a previous study on flare in ankylosing spondylitis showed that, besides acute pain, many patients experienced reduced mobility, fatigue, depression, anger, fear and generalised whole-body reactions felt as a devastating phenomenon.¹⁰ Moreover, patients may disagree with physicians on the magnitude of disease activity worsening required to define a flare. Indeed, in a study by Leeb *et al*, in contrast with physicians' perspectives, patients required greater improvement to feel satisfied, and less worsening to feel dissatisfied.¹¹ Defining a worsening of RA should clearly not depend on only physicians' perspectives.¹²

The Strategy of Treatment in Patients with Rheumatoid Arthritis (STPR) initiative, comprising a group of senior faculty rheumatologists,^{13–15} began a study in 2007 with the goal of developing a self-administered tool to capture RA flare according to the second approach described above: transient or long lasting, present or recent (ie, within the previous 3 months to limit recall bias), regardless of any clinical evaluation by the rheumatologist. In this work, we aimed, through creation of a questionnaire, to define the components constituting RA flare according to patient and physician perspectives, and to develop the domains able to identify and capture such a flare.

METHODS

The study involved developing two comprehensive lists of items that could define flare from a patient and/or a rheumatologist perspective with two qualitative methods: semistructured interviews to elicit patient views, and a Delphi exercise to reach consensus among physicians.

Patient perspective

Before the study, two health psychologists (FB, ES) performed a content analysis based on a non-structured discussion with 10 patients with RA and used their answers to develop the format of subsequent patient interviews that were planned in the main study (see online supplementary text).

Then, eight to ten consecutive patients with established RA (ie, more than 2 years' duration) included in each of the 13 participating rheumatology departments were asked to participate in individual semistructured interviews that explored their feelings and thoughts about RA flare. A research nurse or a health psychologist in each centre conducted 10–15 min interviews, which were recorded for further analysis. All patients received adequate information about the objectives and process of the study and gave their consent to participate before the interview.

Content analysis

The interviews were transcribed on to paper by the two health psychologists (FB, ES), and their content was analysed to identify the attributes patients used to describe RA flare and the frequency with which these elements were cited.

In the first step, the two health psychologists performed an explanatory thematic analysis based on a non-structured discussion with 10 patients, who were asked to describe their usual symptoms and feelings when a disease flare occurs, and 26 themes were initially developed. The eight most frequently reported were finally selected to develop the format of subsequent patient interviews. In the second step, this guide of eight main themes with open questions was an opportunity for 102 other patients to offer their opinions on flare. Over 350 pages, the patients described in detail what they experienced during an RA flare. Codes were developed for latent characteristics that can be reliably applied, and a coding frame was created that contains the label for each code, its definition, and examples of what should and should not be coded with it. To establish the reliability of the coding system, two people then independently used the manual to apply the codes. Finally, the identified attributes were reorganised into discrete domains, each representing a relevant RA flare feature.

Physician perspective

A panel of 13 senior university rheumatologists (all listed among the authors) experienced in the care of patients with RA participated in a Delphi exercise. The rheumatologists were first asked to list the elements that best reflected RA flares, introduced as transient exacerbations of disease activity. They were asked to respond to the following statement: 'By excluding the variations of disease activity due to an end-of-dose effect from a treatment such as biotherapy, please state the elements that you consider to best describe or represent a flare in an RA patient'. Each expert had to propose at least 10 items during the preliminary round. The proposed items were first organised into several domains and then reduced during a four-round Delphi process in which items were definitively selected when cited by at least 75% of the 13 participants and definitively rejected when cited by fewer than 25% of them. At each round, the remaining items were maintained for the following procedure.

Elaboration of self-administered questionnaire and cognitive testing

Both patient- and physician-reported domains were used to develop the Flare Assessment in Rheumatoid Arthritis (FLARE) self-administered questionnaire. During the final meeting between the senior rheumatologists and the health psychologists in charge of the interview analysis, all domains were collected, and an affirmative statement was formulated for each domain. This format was preferred over an interrogative one, because the latter is usually perceived as intrusive by patients. The response modality was a Likert scale of six answers ranging from 'absolutely true' to 'completely untrue'.

A complementary study was performed in April 2011 on a series of 12 new patients with RA (different from those who were involved in the previous interviews), who were asked first to read the questionnaire. These 12 patients were asked whether they felt that this questionnaire described a flare, 'their' flare, and did not miss any important features of RA flare. They were also asked to read each item separately, and comment on it, by responding to four questions. (1) Is the item suggestive of a flare? (2) Does the wording need improvement? (3) Would you suggest changes in terms? (4) Which item do you feel to be the most important for describing a flare of RA?

RESULTS

Patient perspective

In total, 102 patients were interviewed, and complete data were available for 99. Most patients (61%) reported that a flare usually starts with a feeling of swelling in the joints, and 11% mentioned frozen joints. An increase in pain was cited by all patients, with various qualifications of pain (very strong, 54%; arduous, 7.1%; shooting, 16.1%; unbearable, 19.6%; excruciating, 7.1%) and associated with an increase in daily intake of analgesics (eg, non-steroid anti-inflammatory drugs, steroids) for 82% of patients. During the flare, 66.6% of patients declared feeling depressed, 77% having sleep disturbances, 91% feeling more tired, and 96% reporting repercussions on daily activities. Patients reported feeling loss of independence (87.5%) and emotionally more fragile during the flare (91%). Only 9% of the participants reported flu-like symptoms.

From this content analysis, we selected 10 domains to describe RA flare according to the patient perspective. Six answer modalities were proposed for these 10 items, which allowed detection of items over the preceding 3 months (table 1).

Physician perspective

In the first Delphi round, the rheumatologists proposed 105 items, which were homogenised to 19 items and organised into 14 domains, then used for subsequent rounds. The Delphi process required four additional rounds to obtain converging results in which all domains were accepted by more than 75% of the respondents. Finally, eight domains were selected, one biological and seven clinical.

Development of the FLARE self-administered questionnaire

Among the 10 patient-reported domains and the eight physician-reported ones, four were the same: joint swelling, pain, sleep disturbance and intake of analgesics. During the final meeting, the common domains were merged. A domain relative to biological work-up abnormalities—mentioned by the physicians—was eliminated because it did not fit with the framing of a self-administered questionnaire.

All the remaining domains were used to build the questionnaire. For each domain, the group of physicians and health psychologists developed a statement presenting the concept of the domain. The statements were homogeneously formulated and introduced as follows: 'In the last 3 months, or at some time since the last medical consultation, < statement >'. For each statement, the respondent had to indicate agreement by choosing on a Likert scale one of six possible answers from 'absolutely true' to 'completely untrue'. The English version of the FLARE self-reported questionnaire is presented in table 2, and the original French version in table 3.

Responses to the complementary study

The hierarchy of responses for the question 'which item do you feel to be one of the most important for describing a flare of RA' was: item 5 (7/12 patients selected it as 'one of the most important'), items 3, 4, 8, 9, 10, 11, 12 (selected by 6/12 patients), items 1, 13 (selected by 5/12 patients), items 2, 6 (selected by 4/12 patients), and item 7 (selected by 3/12 patients). In other words, items 8–13 (selected only by the first set of 102 patients) were as often considered as 'the most important' in this complementary study as items 1–7 (selected only by the physicians).

DISCUSSION

We developed a self-administered tool that aims to detect RA flares between two medical consultations. The FLARE questionnaire should be appropriate for identifying any increase in RA disease activity regardless of its duration (transient or long lasting). However, this tool still needs to be validated, and its ability to ensure a tighter adjustment of treatments to the overall activity of RA between two visits will also need further assessment. In its final version, it should be suitable for clinical research and might be for daily clinical practice.

The concept of flare usually differs according to patient and physician perspectives. Patients focus on subjective changes such as pain, general signs, mood disturbance and the need to seek help.⁵ Physicians are more likely to consider objective changes on which they can base treatment decision-making.

Table 1 Items important to consider in the definition of rheumatoid arthritis flare (new onset or increase in disease) elicited during patient semistructured interviews and the Delphi consensus method for physicians

Patient perspective		Physician perspective	
Selected items	Frequency (%)		Frequency (%)
Joint swelling	50	Joint swelling	100
Severe or unbearable joint pain	61	Joint pain level	100
Night awakening by pain	81	Night awakening by pain	92
Daily dose of analgesics	26	Daily dose of analgesics	77
Fatigue	93	Morning stiffness	92
Could not 'do a thing'	18	Patient global assessment of arthritis	100
Increased need for help	86	C-reactive protein level or erythrocyte sedimentation rate	100
Withdrawal, wish to stay alone	19	Daily dose of steroids	77
Feeling depressed	74		
Irritability	53		
Non-selected items			
		Extra-articular manifestations	62
		Disability, work limitation	46
		Joint imaging (eg, ultrasound)	38
		Physician global assessment	38
		Feeling of an arthritic flare	

'Non-selected items' refer to items not selected during the last round of the Delphi process in the list devoted to the rheumatologists' perspective, as fewer than 75% of rheumatologists accepted them in this round (62%, 46%, 38%). Conversely, all attributes identified during the analysis of the semistructured interviews were kept in the patient's list.

Table 2 The FLARE self-administered questionnaire

Information before scale completion: this questionnaire has been designed to be completed by the patient him/herself or by the physician asking the questions during a consultation In the last 3 months (or at some time since the last consultation) please indicate how true the statements below are for you personally (please tick the number)

1 - You noticed the appearance or worsening of morning stiffness in joints over several consecutive days					
Absolutely true	True	Fairly true	Not really true	Untrue	Completely untrue
☐	☐	☐	☐	☐	☐
2 - You noticed the appearance or worsening of pain in one or several joints over several consecutive days					
Absolutely true	True	Fairly true	Not really true	Untrue	Completely untrue
☐	☐	☐	☐	☐	☐
3 - You noticed the appearance or worsening of swelling in one or several joints over several consecutive days					
Absolutely true	True	Fairly true	Not really true	Untrue	Completely untrue
☐	☐	☐	☐	☐	☐
4 - You noticed the worsening of your sleep because of arthritic pain over several consecutive nights					
Absolutely true	True	Fairly true	Not really true	Untrue	Completely untrue
☐	☐	☐	☐	☐	☐
5 - You noticed a marked worsening in your arthritis lasting several consecutive days					
Absolutely true	True	Fairly true	Not really true	Untrue	Completely untrue
☐	☐	☐	☐	☐	☐
6 - You increased your doses of pain killers or anti-inflammatory medication over several consecutive days (If you are not taking any pain killer, select 'Completely untrue')					
Absolutely true	True	Fairly true	Not really true	Untrue	Completely untrue
☐	☐	☐	☐	☐	☐
7 - You increased your daily dose of prednisone for several consecutive days (If you are not taking prednisone, select 'Completely untrue')					
Absolutely true	True	Fairly true	Not really true	Untrue	Completely untrue
☐	☐	☐	☐	☐	☐
8 - You felt particularly tired for several consecutive days because of your rheumatic disorder					
Absolutely true	True	Fairly true	Not really true	Untrue	Completely untrue
☐	☐	☐	☐	☐	☐
9 - You were so restricted that you have decreased your daily activity over several consecutive days because of your rheumatic disorder					
Absolutely true	True	Fairly true	Not really true	Untrue	Completely untrue
☐	☐	☐	☐	☐	☐
10 - You felt more irritable than usual over several consecutive days because of your rheumatic disorder					
Absolutely true	True	Fairly true	Not really true	Untrue	Completely untrue
☐	☐	☐	☐	☐	☐
11 - You felt depressed over several consecutive days because of your rheumatic disorder					
Absolutely true	True	Fairly true	Not really true	Untrue	Completely untrue
☐	☐	☐	☐	☐	☐
12 - You felt you wanted to withdraw and be alone over several consecutive days, because of your rheumatic disorder					
Absolutely true	True	Fairly true	Not really true	Untrue	Completely untrue
☐	☐	☐	☐	☐	☐
13 - You felt an increased need for help over several consecutive days, because of your rheumatic disorder					
Absolutely true	True	Fairly true	Not really true	Untrue	Completely untrue
☐	☐	☐	☐	☐	☐

FLARE, Flare Assessment in Rheumatoid Arthritis.

Table 3 The FLARE self-administered questionnaire in French

Auto-questionnaire FLARE

Information préalable au remplissage du questionnaire: Ce questionnaire a été créé de telle manière qu'il peut soit être rempli par le patient seul, soit par le médecin qui recueille les réponses aux questions posées

Durant les 3 derniers mois (ou depuis la dernière consultation), veuillez indiquer jusqu'à quel point les affirmations ci-dessous sont vraies pour vous (merci d'entourer le chiffre correspondant)

1 - Vous avez constaté l'apparition ou l'aggravation d'un dérouillage matinal articulaire pendant plusieurs jours de suite					
Tout à fait vrai	Vrai	Plutôt vrai	Plutôt faux	Faux	Tout à fait faux
☐	☐	☐	☐	☐	☐

2 - Vous avez constaté l'apparition ou l'aggravation de douleurs d'une ou plusieurs articulations pendant plusieurs jours de suite					
Tout à fait vrai	Vrai	Plutôt vrai	Plutôt faux	Faux	Tout à fait faux
☐	☐	☐	☐	☐	☐

3 - Vous avez constaté l'apparition ou l'aggravation du gonflement d'une ou plusieurs articulations pendant plusieurs jours de suite					
Tout à fait vrai	Vrai	Plutôt vrai	Plutôt faux	Faux	Tout à fait faux
☐	☐	☐	☐	☐	☐

4 - Vous avez constaté l'apparition ou l'aggravation de réveils plusieurs nuits de suite à cause des douleurs de votre polyarthrite					
Tout à fait vrai	Vrai	Plutôt vrai	Plutôt faux	Faux	Tout à fait faux
☐	☐	☐	☐	☐	☐

5 - Vous pensez que votre polyarthrite s'est aggravée de façon nette pendant plusieurs jours de suite					
Tout à fait vrai	Vrai	Plutôt vrai	Plutôt faux	Faux	Tout à fait faux
☐	☐	☐	☐	☐	☐

6 - Vous avez augmenté vos prises de médicaments contre la douleur (antalgiques ou anti-inflammatoires) pendant plusieurs jours de suite (Si vous ne prenez aucun médicament contre la douleur, cochez « 0 »)					
Tout à fait vrai	Vrai	Plutôt vrai	Plutôt faux	Faux	Tout à fait faux
☐	☐	☐	☐	☐	☐

7 - Vous avez augmenté vos prises de cortisone pendant plusieurs jours de suite du fait de votre polyarthrite (Si vous ne prenez pas de cortisone, cochez « 0 »)					
Tout à fait vrai	Vrai	Plutôt vrai	Plutôt faux	Faux	Tout à fait faux
☐	☐	☐	☐	☐	☐

8 - Vous vous êtes senti(e) très fatigué(e) pendant plusieurs jours de suite du fait de votre polyarthrite					
Tout à fait vrai	Vrai	Plutôt vrai	Plutôt faux	Faux	Tout à fait faux
☐	☐	☐	☐	☐	☐

9 - Vous avez été tellement limité(e) que vous ne pouviez « plus rien faire » pendant plusieurs jours de suite du fait de votre polyarthrite					
Tout à fait vrai	Vrai	Plutôt vrai	Plutôt faux	Faux	Tout à fait faux
☐	☐	☐	☐	☐	☐

10 - Vous vous êtes senti plus irritable pendant plusieurs jours de suite du fait de votre polyarthrite					
Tout à fait vrai	Vrai	Plutôt vrai	Plutôt faux	Faux	Tout à fait faux
☐	☐	☐	☐	☐	☐

11 - Vous avez ressenti une baisse de moral pendant plusieurs jours de suite du fait de votre polyarthrite					
Tout à fait vrai	Vrai	Plutôt vrai	Plutôt faux	Faux	Tout à fait faux
☐	☐	☐	☐	☐	☐

12 - Vous avez eu envie de vous replier sur vous-même ou de vous isoler pendant plusieurs jours de suite du fait de votre polyarthrite					
Tout à fait vrai	Vrai	Plutôt vrai	Plutôt faux	Faux	Tout à fait faux
☐	☐	☐	☐	☐	☐

13 - Vous avez ressenti un plus grand besoin d'aide pendant plusieurs jours de suite du fait de votre polyarthrite					
Tout à fait vrai	Vrai	Plutôt vrai	Plutôt faux	Faux	Tout à fait faux
☐	☐	☐	☐	☐	☐

FLARE, Flare Assessment in Rheumatoid Arthritis.

Different scientific organisations such as the OMERACT group, the American College of Rheumatology or the European League Against Rheumatism have recommended considering both perspectives because they are usually not redundant,^{16 17} but often complement each other. This recommendation was confirmed in our work because only four of the 10 patient-proposed items and eight physician-proposed items were common to both types of respondent: joint swelling, pain, sleep disturbance and intake of analgesics.

The FLARE self-administered questionnaire is also complementary to the rheumatologist examination (eg, joint counts or disease activity score using 28 joint counts) because it collects information about disease activity that occurred between two consultations and may be absent at the time of the visit to the physician.

The FLARE instrument may also be useful for patients to self-detect a flare and subsequently ask for a prompt appointment, although thresholds could vary according to the patient. Indeed, Hewlett *et al*¹⁸ showed in a 6-year prospective trial that patients with RA who initiated their reviews through direct access were clinically and psychologically at least as well as patients with traditional reviews initiated by physicians. Moreover, the former patients requested fewer appointments (more than one-third fewer medical appointments), which reduced the overall use of restricted healthcare resources.¹⁸

Many chronic diseases can be punctuated by exacerbations. These exacerbations are not always captured by activity scores, which are obtained only during scheduled visits and require physician assessment and/or blood sampling (erythrocyte sedimentation rate or C-reactive protein measurement). Fluctuations of sufficient duration could affect radiographic and functional outcome.⁸ 'Flare' is commonly used by patients and clinicians to describe a worsening of symptoms and is encountered in various autoimmune diseases such as atopic dermatitis,¹⁹ ankylosing spondylitis,⁹ juvenile arthritis,^{20 21} lupus^{22 23} and gout.²⁴ Numerous efforts have aimed to define validated end points for improvement in RA in RCTs or in daily practice, but no thresholds have been set to define a significant worsening of disease activity.⁵ Accordingly, although 'RA flare' is conceptually recognised, evidence is limited and a consensual definition is lacking.^{5 7} This absence is not restricted to RA, because a definition of gout flare has not yet been validated, even though gout has been described since antiquity²⁴ and experienced by millions of patients; nevertheless, patients are treated and cured.

The OMERACT group defined flare in RA as 'a cluster of symptoms of sufficient duration and intensity that cannot be self-managed by the patient and require initiation, change or increase in therapy'.^{5 7} This definition does not explicitly consider the possibility of a return to disease baseline ('end of flare'), because the authors sought to build a tool for RCTs first (to recognise as soon as possible loss of efficacy of treatments or quantitatively characterise reasons for study withdrawal on the basis of loss, or lack, of efficacy),⁵ although the ultimate goal is also to enhance clinical care.⁶ Our work seems to be complementary to the OMERACT initiative, which involves some of the STPR members. Although based on a slightly different concept of flare and different methodology, the preliminary results of the OMERACT project and our results are consistent.

At least six issues remain unresolved. First, no threshold of disease worsening has been established to define a flare, which may be explained by the perception of the severity of flare differing between patients, and for a single patient from time to time. This variation in severity of flare prompted us to propose

a Likert scale with six possible answers for each question, which offers the opportunity to express the final result of the 'flare instrument' quantitatively (as a score) or qualitatively (flare or no flare, according to a threshold for flare). This format has still to be defined and tested against an anchor assessment of RA activity by another score with previously established thresholds of significance, such as routine assessment of patient index data (RAPID)-3, which can be longitudinally fulfilled by the patients on a home-made basis.²⁵

Second, the duration of symptom exacerbation remains to be clarified. Our patient interviews revealed significant variations in the defined duration of flare, ranging from a few days to a couple of weeks or months. These discrepancies have been observed in other diseases.^{10 19 21} The scientific community has identified an area for research, because definition of a 'sufficient duration' (to lead to structural damage) may be as important as the definition of flare itself. While waiting for such a definition, we chose to capture any flare the patient remembered, regardless of its duration or recurrence.

The third issue relates to the ability of patients to correctly remember with sufficient accuracy all events occurring between two clinic visits. We chose a period of 3 months because it is the delay most often considered optimal in RA care. A longer period could be subjected to a stronger memory bias. Indeed, previous studies have shown that retrospective evaluation of pain within the past week or month already leads to a slight overestimation of pain actually experienced during those short periods.^{26 27} However, patients with RA seemed to more correctly recall and report flare frequency and pain intensity than other painful conditions.^{26 28–30} However, problems could arise with features other than pain, especially general features (flu-like symptoms), which are probably forgotten even more quickly than worsening of pain. This situation may be illustrated by only a few of our patients focusing on this aspect, although it has been emphasised in group meetings of patients.^{5 10}

The fourth limitation (inherent to the choice of a self-administered tool also allowing the detection of flares between two visits) was the need to discard both biological results and physicians' global assessment from the list of items first selected by physicians during the Delphi process.

The fifth issue is that this questionnaire has only been developed in the French language, with the input of French physicians and patients. Trans-cultural differences in the meaning of 'flare' might have led to the selection of different items or wordings in other languages or settings.

Last, whether the patients perceive the questions as only related to their arthritis/condition, or as a result of other outside forces, has not been tested.

This tool needs to be validated in a prospective trial of patients with three main objectives: (1) the validity of the tool³¹ (internal validity, measured with a multiple factorial analysis, and a Rasch model, the external validity being evaluated by correlation scores with the RAPID and the rheumatoid arthritis impact of disease score); (2) the reliability and responsiveness of the tool (reproducibility, sensitivity to change, and effect of the tool on decision)³¹; and (3) the feasibility of using this score,³¹ even in daily practice. Then, the predictive capacity of the tool must be evaluated.

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