EXTENDED REPORT

A patient-derived and patient-reported outcome measure for assessing psoriatic arthritis: elaboration and preliminary validation of the Psoriatic Arthritis Impact of Disease (PsAID) questionnaire, a 13-country EULAR initiative

Laure Gossec,[1] Maarten de Wit,[2] Uta Kiltz,[3] Juergen Braun,[3] Umut Kalyoncu,[4] Rossana Scrivo,[5] Mara Maccarone,[6] Laurence Carton,[7] Kati Otsa,[8] Imre Sooäär,[9] Turid Heiberg,[10] Heidi Bertheussen,[11] Juan D Cañete,[12] Anselm Sánchez Lombarte,[13] Andra Balanescu,[14] Alina Dinte,[15] Kurt de Vlam,[16] Josef S Smolen,[17,18] Tanja Stamm,[18,19] Dora Niedermayer,[20] Gabor Békés,[21] Douglas Veale,[22] Philip Helliwell,[23] Andrew Parkinson,[24] Thomas Luger,[25] Tore K Kvien,[26] On behalf of the EULAR PsAID Taskforce

ABSTRACT

Introduction The objective was to develop a questionnaire that can be used to calculate a score reflecting the impact of psoriatic arthritis (PsA) from the patients' perspective: the PsA Impact of Disease (PsAID) questionnaire.

Methods Twelve patient research partners identified important domains (areas of health); 139 patients prioritised them according to importance. Numeric rating scale (NRS) questions were developed, one for each domain. To combine the domains into a single score, relative weights were determined based on the relative importance given by 474 patients with PsA. An international cross-sectional and longitudinal validation study was performed in 13 countries to examine correlations of the PsAID score with other PsA or generic disease measures. Test–retest reliability and responsiveness (3 months after a treatment change) were examined in two subsets of patients.

Results Two PsAID questionnaires were developed with both physical and psychological domains: one for clinical practice (12 domains of health) and one for clinical trials (nine domains). Pain, fatigue and skin problems had the highest relative importance. The PsAID scores correlated well with patient global assessment (N=474, Spearman r=0.82–0.84), reliability was high in stable patients (N=88, intraclass correlation coefficient=0.94–0.95), and sensitivity to change was also acceptable (N=71, standardised response mean=0.90–0.91).

Conclusions A questionnaire to assess the impact of PsA on patients' lives has been developed and validated. Two versions of the questionnaire are available, one for clinical practice (PsAID-12) and one for clinical trials (PsAID-9). The PsAID questionnaires should allow better assessment of the patient's perspective in PsA. Further validation is needed.

INTRODUCTION

Assessments based on patients' opinion—patient-reported outcome measures (PROMs)—have received increasing recognition as being critically important end points in both clinical trials and long-term observational studies in rheumatic diseases during the last decade.[1–4] PROMs are elicited directly from the patient and assess how the patient feels or functions with respect to their health condition. These measures reflect the patient burden of disease.[5–6]

Psoriatic arthritis (PsA) is a heterogeneous disease with high impact on patients' lives.[7][8] However, studies on patient-reported outcomes in PsA have been limited.[9–12] PROMs used in PsA clinical trials are mostly generic or adapted from rheumatoid arthritis (RA), and few disease-specific PROMs for PsA are currently available.[13][14] The core set of domains of health proposed by physician experts to be included in randomised clinical trials and observational studies of PsA includes the following PROMs: pain, patient global assessment, physical function and health-related quality of life.[15] Fatigue is considered here as a research item.[15][8][16] And, indeed, a literature review[17] of recently published articles indicated that the only patient-reported outcomes frequently reported were those in the core set, in particular physical function (in 48% of publications, usually using the Health Assessment Questionnaire (HAQ)[18]), but also pain (47%) and patient global assessment (40%). Fatigue was rarely reported (15%), and psychological aspects were not reported at all.[17]

However, other dimensions of health may be important from the patients' perspective.[19][20][3–4] PROMs for PsA were an item on the research agenda resulting from the recent development of the European League Against Rheumatism (EULAR) recommendations for the management of PsA.[21] Subsequently, EULAR agreed to support the development of a new questionnaire and score to better assess patient-reported outcomes in this disease, in line with the previous development of a similarly focused tool for patients with RA.[22][23]

The objectives of this study were to elaborate and validate a disease impact questionnaire for PsA based on patients' experience of the impact of the disease on domains or dimensions of health.

MATERIALS AND METHODS

Elaboration and validation of the PsA Impact of Disease (PsAID) questionnaire were performed in 2011–2012 in three steps (as summarised in online supplementary figure S1), adapting the methodology developed for a similar questionnaire in RA, the RA Impact of Disease (RAID) score.[22 23] The entire process was very much driven by the patient perspective: the group included 12 patient research partners from 12 European countries, two of whom (MdW, MM) were also part of the steering committee. Many of the patient research partners are coauthors of this paper. The patient research partners all had personal experience of PsA and were fluent in English, but had varying experience in research partnership.[24 25] Their input was key at all stages of the project (for more information, see online supplementary text).

Step 1: identification and selection of candidate domains for the PsAID score

Initial choice of domains

A literature review summarising published criteria, measures and questionnaires used in trials of PsA was presented to the 12 patient research partners.[17] During a subsequent 2 h 'focus group' type meeting (where group discussions took place and notes were taken), the participants identified important domains of health in PsA in terms of impact on life, based on their personal experience. For each domain, a brief explanation was elaborated by the group.

Prioritisation of the domains

A priority exercise was performed during February to April 2011 to obtain an order of importance of the domains of health identified by the 12 research partners. The objective of this exercise was to improve external validity and to possibly reduce the number of domains. This part of the elaboration was designed as an international cross-sectional study in 140 patients with definite PsA (10 per investigator/centre), but without any other selection criteria. The names of the domains obtained in the previous step were translated by the investigators and patient partners into each language with a brief explanation and presented as a list in random order. Participants were asked to give an order of decreasing importance to the domains of health and to give a priority rating to those domains they found to be of priority (priority could be attributed to any number of domains by the patients). Additional domains of health could also be commented on. The 12 highest-rated domains were retained (see Results section for more information) for the next step after extensive discussions within the group (ie, with the health professionals and the 12 patient research partners).

Step 2: elaboration and translation of questions to measure the candidate domains

The experts selected or elaborated one question to assess each of these 12 domains of health (January to June 2011). These experts were 14 physicians (including one dermatologist) and two health professionals from 13 European countries and the 12 patient research partners.

Through a data-driven process, after an extensive literature review of published questionnaires, a numeric rating scale (NRS) was selected and modified for our purposes for each domain.[26] When no question in the literature was found satisfactory, a question was developed de novo by the group, with much thought devoted to the wording in English. A translation/validation process was performed subsequently under the responsibility of the national principal investigator. This process followed published recommendations and included two separate translations, simple consensus, back-translation and cross-cultural validation by a multidisciplinary consensus committee and pretesting on five patients.[27 28]

Step 3: weighting and validation study

Overall organisation

A cross-sectional international observational study with a longitudinal component for reliability and sensitivity to change was performed in 13 countries. Applicable general and local regulations were respected, and the project was endorsed or approved by ethics committees in each participating country. The inclusion criteria and data collected are described below. During a meeting in 2012, the results were discussed, and decisions were taken within the group (11 health professionals and nine patient research partners were present at this meeting). Thus, final decisions regarding the items of the PsAID score were driven by both data and expert opinion, with important input from the patient research partners.

Patients

Consecutive adult patients with definite PsA examined in rheumatology outpatient clinics in the participating secondary or tertiary care centres (Austria, Belgium, Estonia, Germany, France, Hungary, Ireland, Italy, Norway, Romania, Spain, Turkey and the UK) were included in 2011–2012. It was planned to include at least 400 patients (30–40 from each country) based on experience from validation of the RAID score.[22 23] Selection criteria were as follows: definite PsA according to the rheumatologist,[29] ability to fill in a questionnaire, and signed informed consent. We aimed to include patients with a range of disease severities and treatments. Patients with other concomitant inflammatory disease(s) and/or severe comorbidities (eg, recent stroke, severe cardiac failure, severe neurological disease) that could potentially influence results of assessments were excluded.

Relative importance of each domain of health

We developed a patient-derived weighting system to be able to combine the results of each question into a single score. Thus, the weights given to each question reflect its importance and relevance to the patients.

The participating patients were given the list of domains (translated as needed) and asked to assign a relative weight to each; they were asked to 'distribute' 100 points between the different domains.[22] After the initial selection of 12 domains of health, it was decided also to explore the validation study scores with either nine or 12 domains of health. Thus, the patients had to give weights twice—first 100 points distributed across nine domains and then 100 points across 12 domains.

Assessment of psychometric properties

Psychometric properties were examined according to the OMERACT filter.[30]

Data collection

The patients gave scores on the NRS to the 12 PsAID items and completed the following other relevant health status measures: HAQ,[18] short form (36) generic quality of life scale (SF-36),[31] Dermatology Life Quality Index (DLQI),[32] EuroQol-5D

(EQ-5D),[33] pain visual analogue scale (0–100 mm), and patient global assessment (0–100 mm) assessed by four questions, one for global health and one each for joints, skin and axial symptoms.[34] Demographic data were collected. In parallel, health professionals recorded clinical features of PsA, CASPAR classification criteria,[29] medications, recent erythrocyte sedimentation rate (ESR), and the physical and laboratory examination elements required to calculate the Disease Activity Score: DAS28-ESR.[35]

The patients with longitudinal assessments (reliability and sensitivity of change) were asked a global question at the second data collection about whether their condition was stable, improved or worse compared with baseline (minimal clinically important difference question).[36 37]

Assessment of validity ('truth') of the PsAID score
Face validity was ascertained by feedback from the group and from the five patients testing the questionnaire in each country.

Construct and external validity were assessed by examining cross-sectional correlations of the PsAID score with the other scores.

Assessment of reliability
Patients considered to be in a stable state by the physician and with stable treatment were included in the reliability arm of the study. For this assessment, the patients filled in the questionnaire a second time from home, 2–10 days after the baseline assessment. Only patients reporting themselves to be stable at the second assessment were analysed.[36] The objective was to include 130 patients, 10 per centre, to obtain analysable data from 100 patients (arbitrary sample size, but based on experience from validation of the RAID score).

Assessment of sensitivity to change
Patients who required an essential therapeutic change because of unacceptable clinical disease activity were included. The therapeutic change could be initiation of a synthetic or biological disease-modifying antirheumatic drug (DMARD). Patients were reassessed in the clinic 10–16 weeks after the treatment change. Only patients reporting themselves to be improved on a global change question were analysed.[36 37] It was planned to include 130 patients (10 per centre) in this part of the study, with the estimate of having data to be adequately analysed from 100 patients (arbitrary sample size, but based on experience from validation of the RAID score).

Preliminary cut-off values of the PsAID score
Cut-offs were calculated to define an acceptable symptom state with the PsAID score[38 39] and the minimal clinically important improvement.[36 37]

Statistical analyses
Weights of domains of health in the combined PsAID scores
Mean and median points given to each domain were computed and linearly transformed to a 0–100 range. Ranks of importance of domains (based on these points) were identified in each participating patient —for example, if a domain received 20 points and was the second most important, it was ranked 2, whereas it was ranked 4 if the points were similar but it was the fourth domain. Mean and median ranks were then also computed for the group of patients and linearly transformed to a 0–100 range. In both cases, equal points gave equal weights. These two techniques were discussed with the group, and it was decided to use the ranked analysis as the basis for the final weights, as this

analysis better reflects the relative importance of each domain and gives slightly less importance to the most prioritised domain (pain). The final weights for each domain are expressed as a percentage of the total score —that is, if a domain has a weight of 10%, the result for that domain will contribute 10% of the final PsAID score.

Weights were also analysed, for subgroups of patients according to the CASPAR criteria fulfilment, as sensitivity to gender, to high versus low patient global assessment, to treatment with biological agents or not, and to current psoriasis or not.

Psychometric properties
In the cross-sectional study, the several possible PsAID scores were each assessed for psychometric properties using SAS V.9.2.

Feasibility
Feasibility was assessed in the cross-sectional study using the percentage of missing data for each of the questions, and distributions of scores were examined for identification of floor and ceiling effects.

Truth
Internal consistency was evaluated using Cronbach's α coefficient.[40] Construct validity was determined by Spearman's correlation between the PsAID scores and other measures of disease activity/impact (including patient and physician global assessment, SF-36 summary values (physical component summary and mental component summary), HAQ, DLQI, EQ-5D and DAS28).[18 31–35]

Reliability
This was tested with the intraclass correlation coefficient (ICC) (two-way model, single measure) with a 95% CI. An ICC of more than 0.8 is usually considered to be indicative of excellent reliability. Pearson's correlations were also calculated. Agreement was evaluated by the Bland and Altman approach.[41]

Sensitivity to change
The standardised response mean (SRM) —that is, the mean change from baseline to 2–4 months after the treatment change divided by the SD of the change—was calculated. An SRM >0.8 is considered large. CIs were calculated by bootstrap.

Preliminary cut-off values to interpret the PsAID scores
The cut-off value for patient-acceptable symptom state (PASS) was estimated as the 75% centile of patients considering themselves in an acceptable state at baseline.[38 39] The minimal clinically relevant improvement was estimated using receiver operating characteristic curves, which were plotted using improvement versus no improvement as the outcome, and the minimal clinically relevant improvement was computed as the change score that had maximal sensitivity while maintaining a specificity of 0.80.[42] This measure indicates the degree of change that 80% or more of patients would indicate as important.

RESULTS
Step 1: identification and selection of candidate domains for the PsAID questionnaire
Initial choice of domains
During the initial phase, the patient research partners identified 16 domains of health as reflecting the impact of PsA (table 1).

Table 1 Sixteen domains of health identified as important by 12 patients with PsA and their order of importance and priority ratings based on information from 139 patients with PsA

Domain number (by order of importance)	Domain and short defining statement	Median order of importance (range of importance 1–16)	% patients ordering this domain in the top 8	% patients ordering this domain in the lowest 4	% patients considering this domain a priority
1	*Pain* (pain in joints, spine and skin)	2.56	95	0	84
2	*Skin problems* (including itching)	6.20	65	13	53
3	*Fatigue* (being physically tired, but also mental fatigue, lack of energy)	6.43	74	6	43
4	*Ability to work/leisure* (ability to work and/or do leisure activities)	6.67	67	9	50
5	*Functional capacity* (capacity to perform daily physical activities, loss of independence)	7.23	64	12	46
6	*Feeling of discomfort* (discomfort and annoyance with everyday tasks)	7.58	64	7	26
7	*Sleep disturbance* (sleep quality, sleep interruptions)	7.96	56	25	36
8	*Anxiety, fear and uncertainty* (eg, about the future, treatments, fear of loneliness)	8.42	50	19	33
9	*Coping* (adjustment to the disease, managing, being in charge, making do with the disease)	8.45	53	17	35
10	*Embarrassment and/or shame due to appearance* (feeling embarrassed/ashamed due to appearance)	9.74	40	35	24
11	*Social participation* (participating fully in social activities)	10.01	33	30	23
12	*Depression* (feeling sad or depressed)	10.06	39	32	24
13	*Relationship with family* (relationship with family and/or people very close to you)	10.51	34	44	30
14	*Concentration difficulties* (difficulty concentrating and memorising)	10.61	32	37	19
15	*Rejection and discrimination due to appearance* (being rejected and discriminated against because of appearance)	11.60	22	53	12
16	*Sexual life* (sexual difficulties or dissatisfaction)	11.61	25	52	15

Patients gave each domain both an order of importance (from 1 to 16) and a priority rating (yes/no). The 12 domains with highest median rank were retained, and domain 13 was merged with domain 11 for the final PsAID scores.
PsA, psoriatic arthritis; PsAID, PsA Impact of Disease.

Prioritisation of the domains

The 16 identified domains were ordered by 139 patients with PsA according to their importance and priority for patients (table 1). It was found that nine domains had high importance, the next four domains (embarrassment, social participation, depression, family life) had less importance, and the last three domains (concentration, discrimination, sex life) had low priority. No additional domains were identified at this stage. The entire project group (the health professionals and the 12 patient research partners) decided to move forward with validation of the PsAID score with either the first nine domains or keeping domains up to number 12 (table 1). Furthermore, domain 11 ('social participation') was rephrased after discussions in the project group to include 'family life' (domain 13).

Step 2: elaboration and translation of questions to measure the candidate domains

It was decided to use single questions (assessed by NRS) for each domain, and to assess both an NRS and the HAQ for physical disability.[18] However, in subsequent steps, the HAQ was not found to perform better for psychometric properties than the NRS in the PsAID score. Thus the NRS was retained. The wording and time frame of the single questions were also discussed. Specific wordings were obtained for each question, and a time frame of 1 week was decided on (see online supplementary table S1). The 12 questions were translated into 11 languages (Estonian, Flemish, French, German, Hungarian, Italian, Norwegian, Romanian, Russian, Spanish, Turkish).

Step 3: weighting and validation study

In total, 499 patients participated in this part of the study; 474 had analysable data (table 2). Mean±SD age was 50.4 ±12.6 years, mean disease duration was 9.6±9.4 years; 50.2% were female. The population had, on average, moderate disease activity, and half were treated with biological DMARDs; 75.5% satisfied the CASPAR criteria.[29]

Final decisions taken for the PsAID questionnaire

Comparison of 12 and nine domains in terms of psychometric properties showed no improvement with the three additional domains, and the correlation and agreement between results with nine and 12 domains was high (see online supplementary figure S2). Thus, the nine-item and 12-item scores will provide similar information on a group level. However, the patient partners stated that the last three domains (10–12) had strong face validity because they represent important domains that should not be excluded, in particular from the consultation room where these three domains provide relevant additional information to the individual health professional. Thus, it was decided to keep two versions of the PsAID questionnaire. The shorter version (PsAID-9) is geared to clinical trials, since a shorter questionnaire is more feasible. The longer version (PsAID-12) is geared to clinical practice, as the responses to each question can

Table 2 Description of the 474 patients with PsA participating in the weighting and validation study

Characteristic	Mean (SD) (range) or N (%)*	Range across countries of mean values or proportions†
Female sex	235 (50.2%)	32.5–81.8%
Age, years	50.4 (12.6) (20.8–80.1)	42.6–55.1
Disease duration, years	9.6 (9.4) (0.0–41.9)	5.4–16.2
Formal education, years	12.5 (3.8) (0–20)	9.9–14.9
Proportion of patients fulfilling CASPAR criteria	351 (75.5%)	23.8–94.6%
Current disease-modifying drug	306 (66.8%)	36.5–85.0%
Current biological treatment	202 (46.8%)	23.5–79.1%
Swollen joint count (0–66)	2.4 (4.1) (0–36)	0.6–5.1
Tender joint count (0–68)	5.4 (8.0) (0–52)	1.8–14.0
Current skin psoriasis	286 (65.2%)	10.5–97.3%
DAS28-ESR	2.8 (1.4) (0.0–7.1)	2.2–4.1
HAQ (0–3)	0.81 (0.70) (0–2.75)	0.63–1.01
Patient global assessment (0–10)	4.1 (2.8) (0–10)	2.9–5.1
Pain (0–10)	4.7 (2.9) (0–10)	3.6–6.2
DLQI (0–30)	4.3 (5.7) (0–30)	1.7–8.8
EQ-5D	0.60 (0.30) (−0.59 to 1)	0.47–0.72
SF-36 physical component	37.7 (10.5) (13.5–58.3)	32.1–40.3
SF-36 mental component	47.0 (11.5) (15.1–68.9)	42.9–54.8

Fewer than 10% of the data were missing for all elements except swollen joint count (10.2% missing data), DAS28 (27.0%) and SF-36 (21.9%).
*Percentages are % of available data.
†Range of means or percentages: minimum and maximum values for means or percentages observed in participating countries.
DAS28, Disease Activity Score (28 joints); DLQI, Dermatology Life Quality Index; EQ-5D, EuroQol-5D; ESR, erythrocyte sedimentation rate; HAQ, Health Assessment Questionnaire; SF-36, short form (36) generic quality of life scale.

provide important information to the healthcare provider, which will help in making shared decisions with the patient on a management plan.

Weights of domains of health

The relative importance of the individual domains was decided for both PsAID questionnaires (PsAID-9 and PsAID-12) (table 3): pain, skin problems and fatigue had the highest relative importance in both weighting exercises. Of note, these weights were very stable in the subgroups of patients (sensitivity analyses, data not shown), although, as expected, weights of questions related to skin were higher in patients with current psoriasis. For PsAID-12 (developed for clinical practice), a simplified weighting system was chosen so that calculation of the final aggregate score does not entail the use of a calculator (tables 3 and 4 and see online supplementary table S1).

Psychometric properties
Feasibility

The percentage of missing data was very low (1%), and floor and ceiling effects were also very low (respectively, 1% and 0%).

'Truth'

The scores using nine and 12 domains had very similar internal consistency (Cronbach's α 0.93–0.94) and similar correlations with other scores, and correlations were, as expected, higher with other PROMs, particularly with patient global assessment, than with physician-derived scores (table 5).

Test–retest reliability

A total of 107 patients had a second assessment for reliability, but only 88 were analysed who all estimated themselves to be in a stable state. Reliability was high and similar for the two possible PsAID scores. The ICCs for the PsAID-12 and PsAID-9 questionnaires were 0.95 (95% CI 0.92 to 0.96) and 0.94 (95%

CI 0.91 to 0.96), respectively. These results were consistent with results for other widely used measures (eg, ICC of HAQ was 0.97 (0.95 to 0.98) in the same population). Corresponding results for Pearson correlation were 0.91 (95% CI 0.86 to 0.93) for PsAID-9, 0.90 (0.86 to 0.93) for PsAID-12, and 0.96 (0.95 to 0.97) for HAQ.

Sensitivity to change

This was assessed in 105 patients, but only 71 estimated themselves to be improved and were analysed. Half were started on a biological DMARD and half on a conventional synthetic

Table 3 Domains of health in the PsAID questionnaires with their relative importance as a percentage: results from the weighting exercise

Domain of health	Relative importance in the PsAID-12 score for clinical practice	Relative importance in the PsAID-9 score for clinical trials
Pain	15	17.4
Fatigue	10	13.1
Skin problems	10	12.1
Work and/or leisure activities	10	11.0
Functional capacity	10	10.7
Discomfort	10	9.8
Sleep disturbance	10	8.9
Coping	5	8.7
Anxiety	5	8.5
Embarrassment and/or shame	5	NA
Social participation	5	NA
Depression	5	NA

NA, not applicable; PsAID, Psoriatic Arthritis Impact of Disease.

Table 4 Calculation modalities of the PsAID scores

	Calculation	Dealing with missing data
PsAID-9	PsAID final value=(PsAID1 (pain) NRS value (range 0–10)×0.174)+(PsAID2 (fatigue) NRS value (range 0–10)×0.131)+(PsAID3 (skin) NRS value (range 0–10)×0.121)+(PsAID4 (work and/or leisure activities) NRS value (range 0–10)×0.110)+(PsAID5 (function) NRS value (range 0–10)×0.107)+(PsAID6 (discomfort) NRS value (range 0–10)×0.098)+(PsAID7 (sleep) NRS value (range 0–10)×0.089)+(PsAID8 (coping) NRS value (range 0–10)×0.087)+(PsAID9 (anxiety) NRS value (range 0–10)×0.085)	If one of the 9 NRS values composing the PsAID is missing, the imputation is as follows: A. Calculate the mean value of the 8 other (non-missing) NRS values (range, 0–10) B. Impute this value for the missing NRS value C. Then, calculate the PsAID as explained above If 2 or more of the NRS values are missing, the PsAID is considered a missing value (no imputation)
PsAID-12	PsAID final value=(PsAID1 (pain) NRS value (range 0–10)×3)+(PsAID2 (fatigue) NRS value (range 0–10)×2)+(PsAID3 (skin) NRS value (range 0–10)×2)+(PsAID4 (Work and/or leisure activities) NRS value (range 0–10)×2)+(PsAID5 (function) NRS value (range 0–10)×2)+(PsAID6 (discomfort) NRS value (range 0–10)×2)+(PsAID7 (sleep) NRS value (range 0–10)×2)+(PsAID8 (coping) NRS value (range 0–10)×1)+(PsAID9 (anxiety) NRS value (range 0–10)×1)+(PsAID10 (embarrassment) NRS value (range 0–10)×1)+(PsAID11 (social life) NRS value (range 0–10)×1)+(PsAID12 (depression) NRS value (range 0–10)×1). The total is divided by 20.	If one of the 12 NRS values composing the PsAID score is missing, the imputation is as follows: A. Calculate the mean value of the 11 other (non-missing) NRS values (range, 0–10) B. Impute this value for the missing NRS value C. Then, calculate the PsAID score as explained above If 2 or more of the NRS values are missing, the PsAID score is considered a missing value (no imputation)

The PsAID calculation is based on NRS questions. Each NRS is assessed as a number between 0 and 10. The range of the final PsAID value is 0–10 where higher numbers indicate worse status. Calculators and translations are available at http://www.eular.org/index.cfm?framePage=/st_com_clinical_tools.cfm.
NRS, numeric rating scale; PsAID, Psoriatic Arthritis Impact of Disease.

DMARD (mainly methotrexate). The SRMs of the PsAID-9 and PsAID-12 scores were 0.90 (95% CI 0.88 to 0.92) and 0.91 (95% CI 0.89 to 0.93), respectively. For comparison, the SRM of HAQ was 0.60 (95% CI 0.58 to 0.62).

Preliminary cut-off values for interpreting the PsAID scores
The PASS cut-off was assessed in 274 patients and was found to be a PsAID-9 value of ≤4.10 and a PsAID-12 value of ≤3.95. Thus, the proposed PASS cut-off is 4 for both scores.

A preliminary value for the minimal clinically important improvement was found to be 3 points (calculations were 3.6 points for change in PsAID-9 and 3.0 points for change in PsAID-12).

The PsAID questionnaires are available online free of charge with their translations in 12 languages (English, Estonian, Flemish, French, German, Hungarian, Italian, Norwegian, Romanian, Russian, Spanish, Turkish) at http://www.eular.org/index.cfm?framePage=/st_com_clinical_tools.cfm

Table 5 Spearman correlations between the PsAID scores and other measures of health status

Comparative measure of health	PsAID-12 correlation R	PsAID-9 correlation R
Patient global assessment	0.843 (p<0.0001)	0.840 (p<0.0001)
Patient global (joints)	0.836 (p<0.0001)	0.845 (p<0.0001)
Patient global (neck, back, hip pain)	0.709 (p<0.0001)	0.711 (p<0.0001)
Patient global (psoriasis)	0.554 (p<0.0001)	0.550 (p<0.0001)
SF-36 aggregated physical score	−0.725 (p<0.0001)	−0.731 (p<0.0001)
SF-36 aggregated emotional score	−0.597 (p<0.0001)	−0.578 (p<0.0001)
HAQ	0.723 (p<0.0001)	0.721 (p<0.0001)
Pain numeric assessment	0.834 (p<0.0001)	0.842 (p<0.0001)
DLQI	0.422 (p<0.0001)	0.408 (p<0.0001)
EQ-5D	−0.758 (p<0.0001)	−0.752 (p<0.0001)
DAS28-ESR	0.547 (p<0.0001)	0.546 (p<0.0001)
Physician global assessment	0.530 (p<0.0001)	0.530 (p<0.0001)

Patient global assessment was evaluated by four global questions.
DAS28, Disease Activity Score (28 joints); DLQI, Dermatology Life Quality Index; EQ-5D, EuroQol-5D; ESR, erythrocyte sedimentation rate; HAQ, Health Assessment Questionnaire; PsAID, Psoriatic Arthritis Impact of Disease; SF-36, short form (36) generic quality of life scale.

DISCUSSION

Two patient-derived questionnaires for assessing the impact of PsA from the patients' perspective are proposed. The longer questionnaire, developed for clinical practice, includes 12 domains of health, each assessed by a single question with response on an NRS. The calculation to obtain a single score result is simplified in order to be feasible for use in the clinic. The shorter questionnaire, developed for clinical trials, includes nine domains of health and appears to bring similar levels of information at the group level. The PsAID scores had satisfactory psychometric properties in an international validation study. These questionnaires, elaborated with the participation of patient research partners, should allow a more thorough quantified assessment of the patient perspective in PsA.

The final selection of domains seems to have good face validity, as pain, skin problems and fatigue appear to be the most important to many patients; however, qualitative studies to confirm the priority of these domains are lacking.[19] Of these three domains, only pain is part of the PsA core set[15] and is regularly reported in PsA studies.[17] Skin problems as experienced by patients and fatigue are originally identified aspects of the disease found in the present study and these domains should be further explored.[16] The other domains of health in the PsAID scores reflect physical, psychological and societal aspects, which is in keeping with the International Classification of Functioning, Disability and Health.[43] Feelings of shame due to physical appearance seem to be more important in patients with PsA than in RA, probably because of the skin component of the disease. Of note, five of the 12 domains of the PsAID questionnaire (ie, 42%) were not previously identified as important in PsA.[17] Patient global assessment was not selected by the people with PsA in the present study, which may indicate that 'patient global' is not a notion that 'makes sense' to patients.[22] The international development of the PsAID scores means that the domains of health assessed in the scores are probably relevant across countries and cultures, but this assumption should also be studied further.[44]

The weights attributed to each domain were based on the patients' scoring of the importance of the domains. We recognise that other approaches could have been applied to weight the domains, but this approach allowed us to score each domain according to its importance for the group of 474 patients included in the study. Regarding external validity of the weights,

it should be noted that, in the validation study, a high percentage of patients were taking biological agents, which reflects the centres involved (secondary or tertiary care rheumatology centres) and the inclusion process—many patients were followed-up in day hospital units. These issues may be a limitation to keep in mind for generalisability. However, the relative importance of the different domains was similar in patients treated with biological agents or not, and in patients with a high or low patient global assessment (results not shown). These observations support the relevance and generalisability of the preliminary PsAID questionnaires.

This study has both strengths and weaknesses. Strengths include the central involvement of patients in the elaboration of the PsAID score and the inclusion of patient research partners with PsA from 12 countries with different cultures and socioeconomic backgrounds. Furthermore, the PsAID questionnaires were validated with more than 470 patients from 13 countries. The scores have good face validity and also potentially good generalisability. Finally, the methodology used to obtain patient-derived weights for combination of the results into a single score is novel for PsA and could be applied in other contexts. It has, for example, now also been used in the elaboration of a Pancreatic Cancer Impact of Disease (PACADI) score.[45] One weakness is that patients had a clinical diagnosis of PsA, and it turned out that 24.5% of the patients in the validation study did not formally fulfil the CASPAR classification criteria.[29] However, weighting results were similar in the subpopulation that did fulfil the CASPAR criteria.

The impact of PsA is usually assessed by levels of pain and patient global assessment.[15 17] Concerns have been raised that these instruments may not adequately capture all patient-relevant data, which was the basis for the development of this new questionnaire. Complex generic or arthritis-specific quality of life instruments such as SF-36[31] and the Arthritis Impact Measurement Scale (AIMS2)[46] capture information on many domains of health, including mental health and social functioning. However, these questionnaires are long, and interpretation of the scores is complex, especially since they do not provide a single score reflecting all domains. However, patient-reported data are strongly collinear, and the new PsAID scores correlate strongly with patient global assessment. Therefore the additional information over the existing indices obtained by adding more variables will need to be further explored at a group level. At the patient level, however, the PsAID-12 questionnaire (for clinical practice) should allow a more precise assessment of the impact of PsA, helping healthcare providers and patients to make shared treatment decisions geared to either disease activity or, for example, psychological distress.

In conclusion, this study enabled us to propose two preliminary patient-derived weighted questionnaires for assessing the impact of PsA. PsAID-9 is viewed as an additional instrument for the assessment of PsA in clinical trials, giving supplementary information on patient-relevant domains of health. The PsAID-12 score will hopefully be valuable in clinical practice, both for identification of areas that should be addressed in clinical management and by monitoring the patients longitudinally. However, further validation of the PsAID score is needed, in particular regarding sensitivity to change in comparison with other outcome measures in PsA.[47]

Author affiliations
[1]Department of Rheumatology, UPMC University Paris 06, GRC-UPMC 08 (EEMOIS) and AP-HP, Pitié Salpêtrière Hospital, Paris, France
[2]Patient Research Partner, People with Arthritis/Rheumatism in Europe (PARE), Zurich, Switzerland
[3]Rheumazentrum Ruhrgebiet, Herne and Ruhr-Universität Bochum, Herne, Germany
[4]Division of Rheumatology, Faculty of Medicine, Hacettepe University, Ankara, Turkey
[5]Dipartimento di Medicina Interna e Specialità Mediche, Reumatologia—Sapienza Università di Roma, Rome, Italy
[6]Patient Research Partner, ADIPSO (Associazione per la Difesa degli Psoriasici)—PEPsoPOF (Pan European Psoriasis Patients' Organization Forum), Rome, Italy
[7]Patient Research Partner, Aflar Patient Association, Paris, France
[8]Rheumatology Department, Tallinn Central Hospital, Tallinn, Estonia
[9]Patient Research Partner, Estonia
[10]Faculty of Health and Social Studies, Regional Research Support, Oslo University Hospital, Oestfold University College, Halden, Norway
[11]Patient Research Partner, Norway
[12]Arthritis Unit, Department of Rheumatology, Hospital Clínic and IDIBAPS, Barcelona, Spain
[13]Patient Research Partner, Spain
[14]Research Center of Rheumatic Diseases, Sf Maria Hospital, University of Medicine and Pharmacy Carol Davila, Bucharest, Romania
[15]Patient Research Partner, Romania
[16]Department of Rheumatology, University Hospitals Leuven, Leuven, Belgium
[17]Division of Rheumatology, Department of Medicine 3, Medical University of Vienna, Vienna, Austria
[18]2nd Department of Medicine, Hietzing Hospital, Vienna, Austria
[19]Division of Rheumatology, Department of Medicine 3, Medical University of Vienna, Vienna, Austria
[20]3rd Rheumatology Department, National Institute of Rheumatology and Physiotherapy, Budapest, Hungary
[21]Patient Research Partner, Hungary
[22]Dublin Academic Medical Centre, St Vincent's University Hospital, Dublin, Ireland
[23]Leeds Institute of Rheumatic and Musculoskeletal Medicine, University of Leeds, Leeds, UK
[24]Patient Research Partner, UK
[25]Department of Dermatology, University Hospital Münster, Münster, Germany
[26]Department of Rheumatology, Diakonhjemmet Hospital, Oslo, Norway

REFERENCES

1 Scoggins JF, Patrick DL. The use of patients reported outcomes instruments in registered clinical trials: evidence from ClinicalTrials.gov. *Contemp Clin Trials* 2009;30:289–92.

2 Kalyoncu U, Dougados M, Gossec L, et al. Reporting of patient-reported outcomes in recent trials in rheumatoid arthritis: a systematic literature review. *Ann Rheum Dis* 2009;68:183–90.

3 Kirwan JR, Minnock P, Adebajo A, et al. Patient perspective: fatigue as a recommended patient centered outcome measure in rheumatoid arthritis. *J Rheumatol* 2007;34:1174–7.

4 Kirwan JR, Bartlett SJ, Beaton DE, et al. Updating the OMERACT filter: implications for patient-reported outcomes. *J Rheumatol* 2014. [Epub ahead of print 1 Mar 2014].

5 Acquadro C, Berzon R, Dubois D, et al. Incorporating the patient's perspective into drug development and communication: an ad hoc task force report of the Patient-Reported Outcomes (PRO) Harmonization Group meeting at the Food and Drug Administration, February 16, 2001. *Value Health* 2003;6:522–31.

6 McLeod LD, Coon CD, Martin SA, et al. Interpreting patient-reported outcome results: US FDA guidance and emerging methods. *Expert Rev Pharmacoecon Outcomes Res* 2011;11:163–9.

7 Strand V, Sharp V, Koenig AS, et al. Comparison of health-related quality of life in rheumatoid arthritis, psoriatic arthritis and psoriasis and effects of etanercept treatment. *Ann Rheum Dis* 2012;71:1143–50.

8 Mease PJ, Antoni CE, Gladman DD, et al. Psoriatic arthritis assessment tools in clinical trials. *Ann Rheum Dis* 2005;64:ii49–54.

9 Armstrong AW, Schupp C, Wu J, et al. Quality of life and work productivity impairment among psoriasis patients: findings from the National Psoriasis Foundation survey data 2003–2011. *PLoS ONE* 2012;7:e52935.

10 MacKenzie H, Thavaneswaran A, Chandran V, et al. Patient-reported outcome in psoriatic arthritis: a comparison of Web-based versus paper-completed questionnaires. *J Rheumatol* 2011;38:2619–24.

11 Mease PJ, Woolley JM, Bitman B, et al. Minimally important difference of Health Assessment Questionnaire in psoriatic arthritis: relating thresholds of improvement in functional ability to patient-rated importance and satisfaction. *J Rheumatol* 2011;38:2461–5.

12 Kwok T, Pope JE. Minimally important difference for patient-reported outcomes in psoriatic arthritis: Health Assessment Questionnaire and pain, fatigue, and global visual analog scales. *J Rheumatol* 2010;37:1024–8.

13 Gladman DD, Helliwell P, Mease PJ, et al. Assessment of patients with psoriatic arthritis: a review of currently available measures. *Arthritis Rheum* 2004;50:24–35.

14 Brodszky V, Péntek M, Bálint PV, et al. Comparison of the Psoriatic Arthritis Quality of Life (PsAQoL) questionnaire, the functional status (HAQ) and utility (EQ-5D) measures in psoriatic arthritis: results from a cross-sectional survey. *Scand J Rheumatol* 2010;39:303–9.

15 Gladman DD, Mease PJ, Strand V, et al. Consensus on a core set of domains for psoriatic arthritis. *J Rheumatol* 2007;34:1167–70.

16 Husted JA, Tom BD, Farewell VT, et al. Longitudinal analysis of fatigue in psoriatic arthritis. *J Rheumatol* 2010;37:1878–84.

17 Palominos PE, Gaujoux-Viala C, Fautrel B, et al. Clinical outcomes in psoriatic arthritis: A systematic literature review. *Arthritis Care Res (Hoboken)* 2012;64:397–406.

18 Bruce B, Fries JF. The Stanford health assessment questionnaire (HAQ): a review of its history, issues, progress, and documentation. *J Rheumatol* 2003;30:167–78.

19 Stamm TA, Nell V, Mathis M, et al. Concepts important to patients with psoriatic arthritis are not adequately covered by standard measures of functioning. *Arthritis Rheum* 2007;57:487–94.

20 Dandorfer SW, Rech J, Manger B, et al. Differences in the patient's and the physician's perspective of disease in psoriatic arthritis. *Semin Arthritis Rheum* 2012;42:32–41.

21 Gossec L, Smolen JS, Gaujoux-Viala C, et al. European League Against Rheumatism recommendations for the management of psoriatic arthritis with pharmacological therapies. *Ann Rheum Dis* 2012;71:4–12.

22 Gossec L, Dougados M, Rincheval N, et al. Elaboration of the preliminary Rheumatoid Arthritis Impact of Disease (RAID) score: a EULAR initiative. *Ann Rheum Dis* 2009;68:1680–5.

23 Gossec L, Paternotte S, Aanerud GJ, et al. Finalisation and validation of the rheumatoid arthritis impact of disease score, a patient-derived composite measure of impact of rheumatoid arthritis: a EULAR initiative. *Ann Rheum Dis* 2011;70:935–42.

24 de Wit MP, Berlo SE, Aanerud GJ, et al. European League Against Rheumatism recommendations for the inclusion of patient representatives in scientific projects. *Ann Rheum Dis* 2011;70:722–6.

25 de Wit MP, Elberse JE, Broerse JE, et al. Do not forget the professional—the value of the FIRST model for guiding the structural involvement of patients in rheumatology research. *Health Expect* 2013. doi:10.1111/hex.12048. [Epub ahead of print].

26 Katz PP. Introduction to special issue: patient outcomes in rheumatology, 2011. *Arthritis Care Res (Hoboken)* 2011;63(Suppl 11):S1–3.

27 Guillemin F, Bombardier C, Beaton D. Cross-cultural adaptation of health-related quality of life measures: literature review and proposed guidelines. *J Clin Epidemiol* 1993;46:1417–32.

28 Beaton DE, Bombardier C, Guillemin F, et al. Guidelines for the process of cross-cultural adaptation of self-report measures. *Spine* 2000;25:3186–91.

29 Taylor W, Gladman D, Helliwell P, et al.; CASPAR Study Group. Classification criteria for psoriatic arthritis: development of new criteria from a large international study. *Arthritis Rheum* 2006;54:2665–73.

30 Boers M, Brooks P, Strand CV, et al. The OMERACT filter for outcome measures in rheumatology. *J Rheumatol* 1998;25:198–9.

31 Jenkinson C, Coulter A, Wright L. Short form 36 (SF36) health survey questionnaire: normative data for adults of working age. *BMJ* 1993;306:1437–40.

32 Finlay AY, Khan GK. Dermatology Life Quality Index (DLQI)—a simple practical measure for routine clinical use. *Clin Exp Dermatol* 1994;19:210–16.

33 Hurst NP, Kind P, Ruta D, et al. Measuring health-related quality of life in rheumatoid arthritis: validity, responsiveness and reliability of EuroQol (EQ-5D). *Br J Rheumatol* 1997;36:551–9.

34 Cauli A, Gladman DD, Mathieu A, et al.; GRAPPA 3PPsA Study Group. Patient global assessment in psoriatic arthritis: a multicenter GRAPPA and OMERACT study. *J Rheumatol* 2011;38:898–903.

35 Helliwell PS, Fitzgerald O, Strand CV, et al. Composite Measures in Psoriatic Arthritis: a report from the GRAPPA 2009 annual meeting. *J Rheumatol* 2011;38:540–5.

36 Aletaha D, Funovits J, Ward MM, et al. Perception of improvement in patients with rheumatoid arthritis varies with disease activity levels at baseline. *Arthritis Rheum* 2009;61:313–20.

37 Wells G, Anderson J, Boers M, et al. MCID/Low Disease Activity State Workshop: summary, recommendations, and research agenda. *J Rheumatol* 2003;30:1115–18.

38 Tubach F, Ravaud P, Beaton D, et al. Minimal clinically important improvement and patient acceptable symptom state for subjective outcome measures in rheumatic disorders. *J Rheumatol* 2007;34:1188–93.

39 Heiberg T, Kvien TK, Mowinckel P, et al. Identification of disease activity and health status cut-off points for the symptom state acceptable to patients with rheumatoid arthritis. *Ann Rheum Dis* 2008;67:967–71.

40 Cronbach LJ, Meehl PE. Construct validity in psychological tests. *Psychol Bull* 1955;52:281–302.

41 Bland JM, Altman DG. Agreement between methods of measurement with multiple observations per individual. *J Biopharm Stat* 2007;17:571–82.

42 Kvamme MK, Kristiansen IS, Lie E, et al. Identification of cutpoints for acceptable health status and important improvement in patient-reported outcomes, in rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis. *J Rheumatol* 2010;37:26–31.

43 Escorpizo R, Kostanjsek N, Kennedy C, et al. Harmonizing WHO's International Classification of Diseases (ICD) and International Classification of Functioning, Disability and Health (ICF): importance and methods to link disease and functioning. *BMC Public Health* 2013;13:742.

44 Skare TL, Bortoluzzo AB, Gonçalves CR, et al. Ethnic influence in clinical and functional measures of Brazilian patients with spondyloarthritis. *J Rheumatol* 2012;39:141–7.

45 Heiberg T, Nordby T, Kvien TK, et al. Development and preliminary validation of the pancreatic cancer disease impact score. *Support Care Cancer* 2013;21:1677–84.

46 Meenan RF, Mason JH, Anderson JJ, et al. AIMS2. The content and properties of a revised and expanded Arthritis Impact Measurement Scales Health Status Questionnaire. *Arthritis Rheum* 1992;35:1–10.

47 Helliwell PS, FitzGerald O, Fransen J, et al. The development of candidate composite disease activity and responder indices for psoriatic arthritis (GRACE project). *Ann Rheum Dis* 2013;72:986–91.