

SPECIAL ARTICLE

Group for Research and Assessment of Psoriasis and Psoriatic Arthritis/Outcome Measures in Rheumatology Consensus-Based Recommendations and Research Agenda for Use of Composite Measures and Treatment Targets in Psoriatic Arthritis

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Objective. A meeting was convened by the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) and Outcome Measures in Rheumatology (OMERACT) to further the development of consensus among physicians and patients regarding composite disease activity measures and targets in psoriatic arthritis (PsA).

Methods. Prior to the meeting, physicians and patients completed surveys on outcome measures. A consensus meeting of 26 rheumatologists, dermatologists, and patient research partners reviewed evidence on

composite measures and potential treatment targets plus results of the surveys. The meeting consisted of plenary presentations, breakout sessions, and group discussions. International experts including members of GRAPPA and OMERACT were invited to the meeting, including the developers of all of the measures discussed. After discussions, participants voted on proposals for use, and consensus was established in a second survey.

Results. Survey results from 128 health care professionals and 139 patients were analyzed alongside a

Supported by AbbVie, Eli Lilly and Company, Pfizer, and Novartis (unrestricted educational grants to the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis).

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Dr. Coates has received consulting fees and/or speaking fees from Amgen, Bristol-Myers Squibb, Celgene, Eli Lilly and Company, Janssen, MSD, Novartis, Pfizer, Prothena, Sun Pharma, and UCB (less than \$10,000 each) and AbbVie (more than \$10,000). Dr. FitzGerald has received consulting fees, speaking fees, and/or honoraria from Bristol-Myers Squibb, Celgene, Janssen, Novartis, Pfizer, and UCB (less than \$10,000 each) and grant support from AbbVie, Bristol-Myers Squibb, and Pfizer. Dr. Merola has received consulting fees and/or speaking fees from Biogen Idec, Janssen, Samumed, Science 37, Celgene, Sanofi Regeneron, Merck, and GlaxoSmithKline (less than \$10,000 each) and AbbVie, Eli Lilly and Company, Novartis, Pfizer, and UCB (more than \$10,000 each). Dr. Smolen has received consulting fees, speaking fees, and/or honoraria from AbbVie, Amgen, AstraZeneca, Astro, Bristol-Myers Squibb, Celgene, Celltrion, Chugai, Gilead, Glaxo, Iltos, Janssen, Eli Lilly and Company, MedImmune, MSD, Novartis-Sandoz, Pfizer, Roche, Samsung, Sanofi, and UCB (less than \$10,000 each). Dr. Boehncke has received consulting fees and/or speaking fees from AbbVie, Almirall, Biogen, Bristol-Myers Squibb, Celgene, Leo, Eli Lilly and Company, Novartis, Pfizer, Sun Pharma, and UCB (less than \$10,000 each). Dr. Callis Duffin has received consulting fees, speaking fees, and/

systematic literature review summarizing evidence. A weighted vote was cast for composite measures. For randomized controlled trials, the most popular measures were the PsA disease activity score (40 votes) and the GRAPPA composite index (28 votes). For clinical practice, the most popular measures were an average of scores on 3 visual analog scales (45 votes) and the disease activity in PsA score (26 votes). After discussion, there was no consensus on a composite measure. The group agreed that several composite measures could be used and that future studies should allow further validation and comparison. The group unanimously agreed that remission should be the ideal target, with minimal disease activity (MDA)/low disease activity as a feasible alternative. The target should include assessment of musculoskeletal disease, skin disease, and health-related quality of life. The group recommended a treatment target of very low disease activity (VLDA) or MDA.

***Conclusion.* Consensus was not reached on a continuous measure of disease activity. In the interim, the group recommended several composites. Consensus was reached on a treatment target of VLDA/MDA. An extensive research agenda was composed and recommends that data on all PsA clinical domains be collected in ongoing studies.**

In 2016, a new core set of outcome measures for psoriatic arthritis (PsA) was developed by the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) and endorsed by the Outcome

or honoraria from Amgen, AbbVie, Celgene, Janssen, Eli Lilly and Company, Pfizer, Novartis, Bristol-Myers Squibb, Stiefel, Xenoport, Boehringer Ingelheim, and AstraZeneca (less than \$10,000 each) and grant support from these companies. Dr. Gladman has received consulting fees from AbbVie, Amgen, Bristol-Myers Squibb, Celgene, Eli Lilly and Company, Janssen, Novartis, Pfizer, and UCB (less than \$10,000 each) and grant support from AbbVie, Amgen, Celgene, Eli Lilly and Company, Novartis, Pfizer, and UCB. Dr. Gottlieb has received consulting fees from Celgene, Bristol-Myers Squibb, Beiersdorf, Novartis, Incyte, Pfizer, Xenoport, Development Crescendo Bioscience, Aclaris, Amicus, Reddy Labs, Valeant, Dermira, Allergan, CSL Behring, Merck, and Sun Pharmaceutical Industries (less than \$10,000 each), Eli Lilly and Company, AbbVie, Janssen, and UCB (more than \$10,000 each), and grant support from Janssen Incyte. Dr. Kavanaugh has received consulting fees and/or honoraria from AbbVie, Amgen, Bristol-Myers Squibb, Celgene, Eli Lilly and Company, Janssen, MSD, Novartis, Pfizer, and UCB (less than \$10,000 each). Dr. Kristensen has received consulting fees and/or speaking fees from Pfizer, AbbVie, Amgen, UCB, Celgene, Bristol-Myers Squibb, MSD, Novartis, Eli Lilly and Company, and Janssen (less than \$10,000 each). Dr. Kvien has received consulting fees and/or speaking fees from AbbVie, Biogen, Bristol-Myers Squibb, Boehringer Ingelheim, Celgene, Celltrion, Eli Lilly and Company, Epirus, Hospira, Merck-Serono, MSD, Mundipharma, Novartis, Oktal, Orion Pharma, Hospira/Pfizer, Roche, Sandoz, and UCB (less than \$10,000 each). Dr. Luger has received consulting fees and/or honoraria from AbbVie, Biogen Idec, Celgene, Ceries, Galderma, Eli Lilly and Company, Janssen-Cilag, La Roche Posay, Maruho, Meda, MSD, Mundipharma, Novartis, Pfizer, Sandoz, Sanofi-Aventis, Symrise, and Wolff (less than \$10,000 each). Dr.

Measures in Rheumatology (OMERACT) group (1). This was the result of a 2-year program of work to establish the key domains for randomized controlled trials (RCTs) and observational studies in PsA. Following acceptance of this core set of domains to be measured, the GRAPPA/OMERACT group is developing the complementary core outcome measures set, which will recommend outcome measures to assess these domains in PsA.

Different groups have been established to examine groups of outcome measures including patient-reported outcomes, musculoskeletal disease activity, skin disease activity, systemic inflammation, imaging, economic cost, and composite disease activity measures. Composite disease activity measures most commonly focus on disease activity and are frequently used in RCTs and increasingly in routine practice to assess outcomes of therapy in PsA and other inflammatory arthritides. While composite measures by definition include multiple components, they can vary significantly in terms of the domains addressed and methods used to combine them into a composite score.

Nearly all composite disease activity measures combine patient-reported outcomes (e.g., patient's assessment of pain, patient's global assessment of disease activity) with physician-assessed outcomes (e.g., joint counts, body surface area of psoriasis). Historically, the composite measures used for PsA have been developed for other diseases, most commonly rheumatoid arthritis (RA), and focus specifically on peripheral arthritis as a single domain. More recently, newer composites have been developed specifically for PsA that have combined outcome measures

McHugh has received consulting fees from AbbVie, Pfizer, UCG, Eli Lilly and Company, Celgene, and Novartis (less than \$10,000 each) and grant support from Celgene, Pfizer, and AbbVie. Dr. Mease has received consulting fees and/or speaking fees from AbbVie, Centocor, Janssen, Merck, Novartis, Pfizer, and UCB (less than \$10,000 each). Dr. Nash has received consulting fees, speaking fees, and/or honoraria from AbbVie, Amgen, Bristol-Myers Squibb, Celgene, Eli Lilly and Company, Janssen, MSD, Novartis, Pfizer, Roche, Sanofi, and UCB (less than \$10,000 each) and grant support from AbbVie, Pfizer, Novartis, Bristol-Myers Squibb, Eli Lilly and Company, and Janssen. Dr. Ogdie has received consulting fees from Pfizer, Novartis, Bristol-Myers Squibb, and Takeda (less than \$10,000 each) and grant support from Novartis and Pfizer. Dr. Rosen has received consulting fees from AbbVie, Celgene, Janssen, Eli Lilly and Company, and Novartis (less than \$10,000 each). Dr. Tillett has received consulting fees and/or speaking fees from AbbVie, Celgene, Janssen, MSD, Novartis, Pfizer, and UCB (less than \$10,000 each). Dr. Veale has received consulting fees, speaking fees, and/or honoraria from AbbVie, Actelion, Bristol-Myers Squibb, Celgene, Janssen, MSD, Pfizer, Roche, and Regeneron/Sanofi (less than \$10,000 each). Dr. Helliwell has received consulting fees and/or speaking fees from AbbVie, Amgen, Bristol-Myers Squibb, Eli Lilly and Company, Janssen, Leo, Novartis, Sun Pharma, and UCB (less than \$10,000 each).

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Submitted for publication August 4, 2017; accepted in revised form November 21, 2017.

in multiple domains (e.g., peripheral arthritis, skin psoriasis, enthesitis) into a single composite to reflect all of the ways in which patients may be affected by their psoriatic disease activity.

The objective of this work was to use multiple methodologies to review composite measures and potential treatment targets in PsA, establishing recommendations and developing a research agenda for future work. Herein, we report the output of a consensus meeting, with discussions focusing on data from the systematic literature review and on pre- and postmeeting surveys of patients and physicians held in 2017.

Methods

Prior to the consensus meeting, 2 surveys were conducted. One survey was sent to health care professional members of GRAPPA to establish current practice internationally with regard to composite measures and targets. A second survey was sent to patients with PsA to establish their experience, what assessments they believed were important, and how they wished to be involved. Patients were recruited internationally, including several GRAPPA patient research partners, members of patient support groups, and patients recruited from clinical practices.

As part of the GRAPPA/OMERACT initiative, a systematic literature review of composite disease activity measures that was a parallel exercise with other groups that were doing a similar process with patient-reported outcomes, clinical disease activity measures, and laboratory and imaging measures. The first part of this initiative was a systematic literature review to identify all composite measures tested in PsA and to assess their validity in this disease. Using data identified and summarized for the systematic literature review, evidence sheets for the composite measures and potential targets were developed for the

consensus meeting attendees. Two different versions were created, 1 for physicians and 1 for patient research partners. These summarized the level of evidence for the measures using the OMERACT filter (2).

On February 10, 2017, a 1-day consensus meeting was held. The meeting had an independent chairperson (Dr. Anne-Maree Keenan, University of Leeds, Leeds, UK) and consisted of plenary presentations, breakout groups, group discussions, and voting. International experts, including members of GRAPPA and OMERACT, were invited to the consensus meeting, including the developers of all of the measures discussed. Twenty-two rheumatologists and dermatologists were invited to ensure that both musculoskeletal and skin manifestations of PsA were considered, and 4 patient research partners from GRAPPA were invited to ensure representation of the patient perspective. At the meeting, key data were presented, including results of the premeeting surveys.

The morning session of the day on which consensus was determined was focused on composite measures of disease activity in PsA. The composite measures discussed were the PsA disease activity score (PASDAS) (3), the GRAPPA composite index (GRACE) (3), the composite psoriatic disease activity index (CPDAI) (4), the disease activity in PsA (DAPSA) score (5), the Routine Assessment of Patient Index Data 3 (RAPID3) (6), and an average of scores on 3 visual analog scales (VAS; patient's assessment of skin disease, patient's global assessment of disease activity, and physician's global assessment of disease activity), termed the 3VAS score.

The afternoon session focused on treating to target and potential targets available in PsA. These targets included cut points of the above composite measures when available but specifically 1) remission/low disease activity using the DAPSA score (7) and 2) the minimal disease activity (MDA) criteria (8) coupled with the more

Table 1. Domains included in the composite measures discussed*

	PtGA	Pain	PhysGA	Joint	Skin	Enthesitis	Dactylitis	Spine	HRQoL	HAQ	CRP
PASDAS	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	No	Yes
GRACE	Yes	Yes	No	Yes	Yes	No	No	No	Yes	Yes	No
CPDAI	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
DAPSA score	Yes	Yes	No	Yes	No	No	No	No	No	No	Yes
3VAS score	Yes	No	Yes	No	Yes	No	No	No	No	No	No
RAPID3	Yes	Yes	No	No	No	No	No	No	No	Yes	No
MDA/VLDA	Yes	Yes	No	Yes	Yes	Yes	No	No	No	Yes	No

* PtGA = patient's global assessment of disease activity; PhysGA = physician's global assessment of disease activity; HRQoL = health-related quality of life; HAQ = Health Assessment Questionnaire; CRP = C-reactive protein; PASDAS = psoriatic arthritis disease activity score; GRACE = Group for Research and Assessment of Psoriasis and Psoriatic Arthritis composite index; CPDAI = composite psoriatic disease activity index; DAPSA score = disease activity in psoriatic arthritis score; 3VAS score = average of scores on 3 visual analog scales (patient's assessment of skin disease, patient's global assessment of disease activity, and physician's global assessment of disease activity); RAPID3 = Routine Assessment of Patient Index Data 3; MDA/VLDA = minimal disease activity/very low disease activity.

stringent very low disease activity (VLDA) criteria (9), because the most validation data had accumulated for these 2 measures. The domains included in these composite measures are shown in Table 1.

For both sessions, after presentation of the key data for the outcome measures, breakout groups were established with representatives from rheumatology and dermatology and the patient research partners to discuss the pros and cons of each measure. These groups then reported back to the complete attendee group. There was then discussion and debate on the different measures with voting on recommendations.

Composite disease activity measures

Physician survey. A total of 128 health care professionals responded, the majority (82%) being rheumatologists. The domains of disease most commonly assessed in clinical practice were joints (97%), dactylitic digits (88%), entheses (87%), pain (86%), C-reactive protein (CRP)/erythrocyte sedimentation rate (86%), and skin (84%). When asked specifically about composite measures, 45% of health care professionals reported that they regularly used a composite measure in their practice, most commonly the MDA criteria or the RAPID3. The majority of respondents thought that a single composite measure was more clinically useful than individual assessment of each domain, and they believed that such composites should include measures of arthritis, enthesitis, and dactylitis, markers of inflammation, and scores on patient's global assessments. The failure to recommend inclusion of a psoriasis assessment is related to the low number of dermatologist respondents. The dermatologists chose skin measures as their top items but included the same measures as the rheumatologists as their subsequent choices.

Patient survey. A total of 139 patients responded. Most reported that they saw their physician every 6 months for assessment, and the majority (84%) reported that their physician assessed only painful or problematic joints rather than performing a formal joint count. Less than one-fourth of patients were asked to complete any questionnaires at or prior to their appointments, although 91% said they would be willing to do so if asked. The most important domains of disease highlighted by the patients were pain (46%), joints (36%), and physical function.

Discussion of measures

Breakout groups were then convened to discuss the following measures: PASDAS, GRACE, CPDAI, DAPSA and the RAPID3 and 3VAS scores. The pros and cons of these measures highlighted by the breakout groups and

subsequent discussions are shown in Table 2. With the exception of DAPSA, the measures are composites covering multiple domains of PsA including peripheral arthritis, skin, dactylitis, enthesitis, axial disease, CRP, function, and health-related quality of life (HRQoL). These data show that the inclusion of skin disease in a composite psoriatic disease measure identifies a treatment effect in psoriatic disease as a whole despite no differential effect on musculoskeletal activity. Some believed that composites covering multiple domains were optimal to quantify the overall burden of disease activity for each patient but clarified that these should then be reported with their individual components to assess each domain as well as total scores.

There was much discussion concerning the outcome measures in general but particularly about whether it is appropriate to include measures of physical function or HRQoL in a disease activity index. These items may be considered measures of impact that are influenced by cumulative damage as well as activity. While it is not ideal to have different measures, the varying feasibility for daily clinical practice and clinical trials was also discussed.

The GRACE was believed to be a valuable composite, but inclusion of the Psoriasis Area and Severity Index (PASI) (11) was believed to be impractical for clinical use. Ideally, the measure of skin disease should be feasible for nondermatologists. Adaptation of the GRACE measure with a simpler skin tool may help, but this would require further validation.

The RAPID3 is a commonly used generic measure of disease activity, used particularly in practices in the US. While the systematic literature review showed preliminary validation in PsA, it was developed for RA and is focused on peripheral joint disease. A modification with a psoriasis VAS (the RAPID3Ps) has also been tested that may be more helpful in patients with significant skin disease.

The 3VAS score was initially developed from the GRACE project but has not been widely published. It consists of an average of 3 VAS: patient's assessment of skin disease, patient's global assessment of disease activity, and physician's global assessment of disease activity. This is quick and feasible but does not include any objective measures of inflammation. Although this is similar in feasibility to the RAPID3, the inclusion of a physician's global assessment of disease activity (which would indirectly require a physician's examination) could be a benefit. However, there is little validation of this measure to date. For both the RAPID3 and the 3VAS score, there was discussion about the potentially significant impact of comorbid fibromyalgia, which may disproportionately affect these composites.

Table 2. Advantages and disadvantages of composite disease activity measures from breakout sessions and discussions*

	Advantages	Disadvantages
DAPSA score	Captures arthritis specifically (different drugs act on different aspects of PsA disease) Can be used with or without CRP Continuous measure States response Responsiveness Relatively simple measure; easy application in practice Feasibility (calculation and conduct) Validated cut points Uses 66/68-joint count	No skin/dactylitis/enthesitis/nails/fatigue Does not capture totality of psoriatic disease (patient-reported outcome) Fatigue/depression not captured Influenced by FMS Arthritis global rather than true global VAS Face validity lacking as other domains of PsA not assessed Composite of articular disease only
PASDAS	Comprehensive Captures many dimensions of the disease Responsive Patient perspective Physician's and patient's global assessments include skin Can give individual scores Includes enthesitis/dactylitis Good cutoff validity Escapes from RA paradigm PsA specific	Not transparent Needs computer to calculate Not currently used much No specific skin measure No specific axial component Fatigue/pain are not captured† No specific measures of participation or functional ability† No reliability data SF-36 has disadvantages (not disease-specific, cost, etc.)
3VAS score	No blood test required Patient centered Simple, speedy, and feasible Includes skin disease, with potential to add nail disease Physician's global assessment (but mandates a joint count) Fits into the PASDAS Potential to add pain to global assessment, following definition	Too easy to manipulate Dangerous for decision making No APRs Effect of patient's global and pain assessments, not disease activity Not specific to enthesitis or axial disease No objective measures No mandated joint count
RAPID3	Includes pain Can be modified to measure skin using the RAPID3Ps Very quick and feasible Only generic disease measure	Includes the HAQ, which may reflect damage as well as activity May be forced to pay for use No objective measures Includes patient measures but no physician's global assessments
GRACE	PsA specific Has face validity Feasible Patient reported with additional measures of joint counts Has components from clinical trials (joint count, PASI) Feasible to translate into clinical practice	No APRs Includes the HAQ Includes the PASI, which has limitations Not as feasible for clinical practice
CPDAI	Includes skin and other relevant domains Modular and adaptable to reflect changes in disease assessment Computerized version (MOPSA) Captures differential response Intuitive; makes sense Does not involve blood tests Delineates mild/moderate/severe disease	No pain/fatigue/patient's global assessment/APRs Cutoffs for skin disease Does not assess nail disease Time consuming, very difficult to do in clinic, but the MOPSA helps (can complete in 6 minutes)

* DAPSA score = disease activity in psoriatic arthritis score; PsA = psoriatic arthritis; CRP = C-reactive protein; FMS = fibromyalgia syndrome; VAS = visual analog scale; PASDAS = PsA disease activity score; RA = rheumatoid arthritis; SF-36 = Short Form 36 health survey; 3VAS score = average of scores on 3 visual analog scales (patient's assessment of skin disease, patient's global assessment of disease activity, and physician's global assessment of disease activity); APRs = acute-phase reactants; RAPID3 = Routine Assessment of Patient Index Data 3; HAQ = Health Assessment Questionnaire; RAPID3Ps = RAPID3 modified with psoriasis VAS; GRACE = Group for Research and Assessment of Psoriasis and Psoriatic Arthritis composite index; PASI = Psoriasis Area and Severity Index; CPDAI = composite psoriatic disease activity index; MOPSA = Measuring Outcome in Psoriatic Arthritis.

† Important outcomes for patients.

The DAPSA score is specifically a measure of peripheral arthritis without inclusion of any other domains. Several attendees commented that this was

a good measure of peripheral arthritis, but separate assessment of skin disease and potentially other domains should be mandated alongside the DAPSA

score to ensure a full assessment of PsA disease activity.

Following the discussion, all attendees (rheumatologists, dermatologists, and patient research partners) voted on the optimal composite scores for RCTs and clinical practice. Each participant had up to 5 votes for the best measure for use in trials and up to 5 votes for the best measure in clinical practice. These could be assigned to 1 measure or distributed across them. The outcome of the vote was spread across measures, with no single measure receiving a strong vote in favor of use in both settings (Figure 1). For use in RCTs, the PASDAS received the highest number of votes ($n = 40$) followed by the GRACE ($n = 28$) and the CPDAI ($n = 25$), while for clinical practice, the 3VAS score received the highest number of votes ($n = 45$) followed by the DAPSA score ($n = 26$) and the CPDAI ($n = 23$). A number of items were identified for the research agenda.

At the end of this session, it was agreed that any measure could be used as long as the patient's disease is fully assessed and patient-reported outcomes are included in the evaluation. It is important to look at how existing composite measures could be modified for future use.

Potential treatment targets

Physician survey. The majority of health care professionals (57%) believed that remission should be the optimal target of treatment, with an alternative of low or minimal disease activity. The most important factors that would influence health care professionals when setting the treatment target included comorbidities (81%), disease activity (79%), and patient goals (65%). At present, 56% of health care professionals reported that they do treat to target in clinical practice, and the 3 most popular targets used are MDA (32%), LDA according to the Disease Activity Score in 28 joints (DAS28) (12) (10%), and remission according to the DAS28 (9.5%). Assessment of joints, HRQoL, and skin and nails were most frequently mentioned as domains to include for a treat-to-target approach.

Patient survey. Again, the majority of patients (56%) agreed that remission or, alternatively, MDA/LDA should be the treatment target, and most patients (45%) defined "remission" as the absence of disease or symptoms. However, the majority (61%) reported that they have not discussed personal goals for managing their PsA with their rheumatologists, and nearly 1 of 5 patients

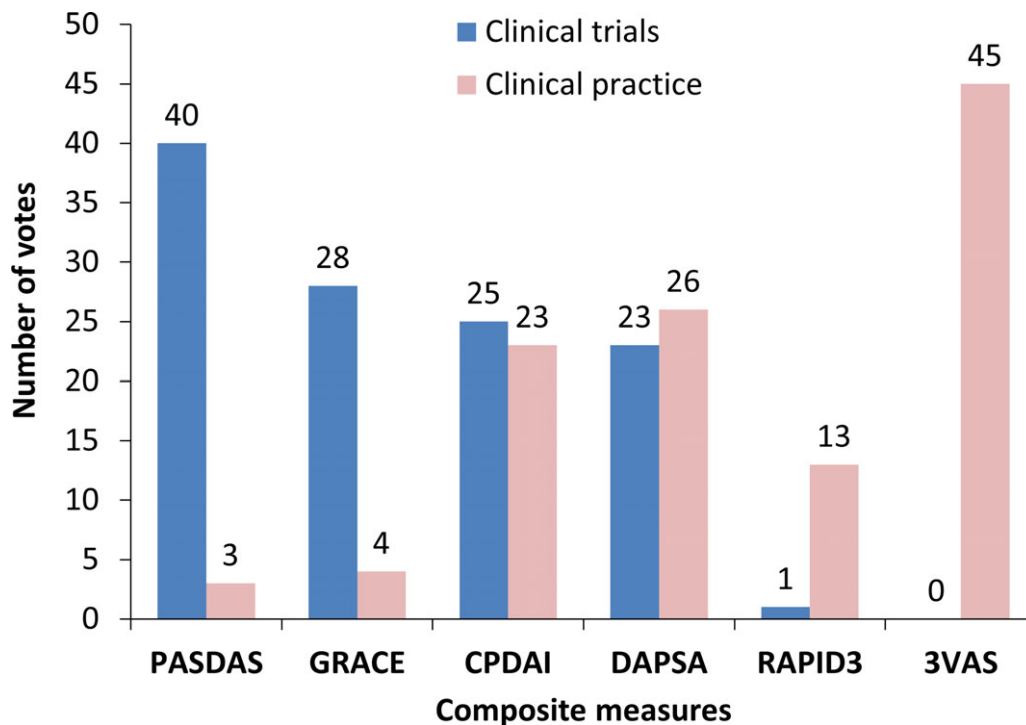


Figure 1. Outcome of a weighted vote on the use of outcome measures in clinical practice and clinical trials. PASDAS = psoriatic arthritis disease activity score; GRACE = Group for Research and Assessment of Psoriasis and Psoriatic Arthritis composite index; CPDAI = composite psoriatic disease activity index; DAPSA score = disease activity in psoriatic arthritis score; RAPID3 = Routine Assessment of Patient Index Data 3; 3VAS score = average of scores on 3 visual analog scales (patient's assessment of skin disease, patient's global assessment of disease activity, and physician's global assessment of disease activity).

wanted their rheumatologists to spend more time listening to their concern.

Discussion of targets

The first discussion was the conceptual target of treatment. The only treat-to-target study in PsA used MDA as the target (13); this is a measure of low disease activity rather than remission. Despite this, the treatment arm had a higher rate of adverse events, so it was discussed that the risks and benefits should be evaluated in the case of each individual patient. Consistent with previous European League Against Rheumatism treatment recommendations (14) and the 2017 treat-to-target task force recommendations

(15), the group agreed unanimously that remission should be the treatment target but that under certain circumstances LDA/MDA is a reasonable alternative.

Breakout groups were then convened to discuss the following targets: VLDA, MDA, modifications of MDA criteria in which some items are mandated, and remission/low disease activity using the DAPSA score. The pros and cons of these measures highlighted by the breakout groups are shown in Table 3.

Given the nature of the disease, the majority of attendees believed that for face validity, any measure of remission or low disease activity should assess multiple domains of disease, particularly peripheral arthritis and skin as these are the most prevalent domains. While rheumatologists tend to prioritize joints over skin when

Table 3. Advantages and disadvantages of PsA target measures from breakout sessions and discussions*

	Advantages	Disadvantages
MDA/VLDA	<ul style="list-style-type: none"> Feasible in practice Simple to perform (no calculations) Derived from patient data Includes global assessment and pain Strong evidence with treat-to-target TICOPA study Responsive to change, correlates with damage, response maintained over time Correlates with patient opinion (PsAID) Modular, so no items can score too highly MDA matches well with PASS and PsAID PASS Includes joints/skin/enthesitis/patient-reported outcomes Does not require CRP for calculation 	<ul style="list-style-type: none"> HAQ score may prevent VLDA Dermatology threshold could be lower, consistent with dermatologist recommendations (body surface area $\leq 1\%$) Heterogeneous in terms of response Binary, not a continuous activity measure MDA can have some skin and joint disease activity Possibility of overtreatment, as VLDA may be difficult to achieve Nails not included No specific measure of axial disease Impact on patient not included at present (e.g., PsAID) Does not include CRP, so should be done separately
MDA modifications	<ul style="list-style-type: none"> Emphasizes skin and/or joints domains MDA composite requires assessment of all key domains Target not a measure Avoids active skin disease if this domain is required (otherwise it can be missed despite MDA) 	<ul style="list-style-type: none"> Includes the HAQ (concern over whether this may reflect damage, not activity; could not be removed/replaced without further research) Consider others (i.e., PFI-10, SF-36, PsAID, PsAQoL) Dermatology threshold could be lower, consistent with dermatologist recommendations (body surface area $\leq 1\%$) Does not include patient-reported outcomes for skin
DAPSA score remission/LDA	<ul style="list-style-type: none"> Feasible in practice Simple to perform (easy calculation) Includes global assessment and pain Exclusion of the HAQ is regarded by some as a positive feature Responsive to change Correlates with damage, states disease activity, response maintained over time Not Boolean restricted Psoriatic disease vs. PsA vs. skin disease Includes CRP 	<ul style="list-style-type: none"> Misses skin and nails Does not measure axial disease or enthesitis Exclusion of the HAQ is regarded by some as a negative feature No data on patient opinion of remission/LDA

* PsA = psoriatic arthritis; MDA/VLDA = minimal disease activity/very low disease activity; HAQ = Health Assessment Questionnaire; TICOPA = tight control of psoriatic arthritis (study); PsAID = PsA Impact of Disease questionnaire; PASS = patient-acceptable symptom state; CRP = C-reactive protein; PFI-10 = Physical Function Items 10; SF-36 = Short Form 36 health survey; PsAQoL = PsA Quality of Life questionnaire; DAPSA score = disease activity in PsA score.

treating their patients with PsA, skin disease is highly important to patients and has great impact on them, with residual skin disease being associated with poorer function and quality of life (16). When considering concepts such as remission, the whole patient should be assessed.

The DAPSA score can be used as both a measure of disease activity and a target. However, DAPSA is designed to measure peripheral arthritis, because it is a composite of joint counts, patient pain, CRP, and a patient's global arthritis score. In some RCTs of biologic agents, the levels of active skin disease and enthesitis in those with disease in remission according to the DAPSA score are similar to VLDA (17). However, in studies of patients with significant baseline skin disease and in recent "real life clinic" data sets, research has shown that patients in DAPSA-defined remission can have significant levels of active skin disease, with an associated impact on HRQoL. Such data are not consistent with the wider concept of remission and undermine the face validity of the concept when using the DAPSA score (18–21). A potential solution would be to require physicians to assess multiple targets for individual measures such as peripheral arthritis and skin disease. However, there is a concern that physicians may not perform all assessments, and therefore active disease would be missed. Research on DAPSA also showed higher levels of residual disease activity than in VLDA/MDA, possibly due to the nature of DAPSA as a summary score, in which one element can be high if the others are low (18–21).

MDA/VLDA is a measure of disease state, not a measure of disease activity; therefore, if MDA is recommended as the target, a different composite of disease activity would still be required. MDA and VLDA criteria do not include a measure of acute-phase reactants that allows calculation before blood results are known. However, it is recommended that acute-phase reactants be tested in addition to the clinical criteria, to aim for normalization in a chronic inflammatory disease (15). The design of the MDA criteria is modular, with each item assessed individually, but because only 5 of the 7 criteria must be met for MDA, residual disease can occur in 1 domain, particularly skin, as only 1 item measures skin disease directly. This is not the case with the VLDA criteria (in which all cut points must be met) or with modifications that require the skin and/or joint items to be met. Concern was raised about the inclusion of the Health Assessment Questionnaire (HAQ) (22) as 1 of the items in the MDA/VLDA criteria. This could potentially prevent patients from achieving VLDA, due to accumulated damage despite adequate control of inflammatory disease activity. However, in this case, the patient would achieve MDA as the alternative target.

Following these discussions on the use of targets in PsA, attendees first voted on the domains that should be considered in a target. The group unanimously agreed that when assessing a target of treatment, there should ideally be assessment of musculoskeletal disease, skin disease, and disease impact/HRQoL.

There was agreement that both the MDA criteria and the DAPSA score had advantages and disadvantages, and that more research should be done. However, in the absence of data, it was agreed that the rheumatology community needs guidance on what to use now to encourage a treat-to-target approach. This was observed with the DAS28 in RA, which was initially not liked but is now widely accepted. Therefore, a motion was proposed that "the group at present recommends a target of treatment as VLDA (remission), or MDA 5/7 as an alternative low/MDA." This was not unanimously supported; there were 21 votes in favor, 2 against, and 1 abstention.

Postmeeting survey

Physician survey. A total of 115 health care professionals, the majority (77%) of whom were rheumatologists, responded to the second survey. Most supported the development of composites but agreed with the advantages and disadvantages listed. Overall, the RAPID3 and 3VAS score were believed to be quick and feasible but not comprehensive enough with no objective measures included. The DAPSA score was feasible but included only assessment of peripheral arthritis and was believed to be more appropriate for polyarticular disease. The GRACE, PASDAS, and CPDAI were believed to be comprehensive but less feasible for routine practice. The balance between including key domains and not being time-consuming was believed to be key. A duration of less than 10 minutes or ideally less than 5 minutes was believed to be reasonable for clinical practice. The CPDAI was the highest ranked (6.4 of 10) for use in clinical practice, but all scores were ranked between 4.5 and 6.5. For RCTs, the CPDAI, PASDAS, and GRACE were believed to be the most appropriate, scoring 6.7, 6.4, and 6.6, respectively, of 10, with the rest being less popular. The vast majority (93%) supported the decision from the meeting that all measures should be studied further, and that data should be collected to allow comparison.

The specific issue of the inclusion of the HAQ in some measures was also addressed. The majority believed that the HAQ could (48%) or should (13%) be included in composites. Most recognized that the HAQ could be influenced by domains other than disease activity, but that "whilst it is affected by damage,

Table 4. Research agenda*

Additional validation data	3VAS score CPDAI GRACE PASDAS CPDAI and/or PASDAS as a target
General	What treat-to-target information measures do trials or regulatory agencies (such as the FDA) need, as these may need to be included in composite measures? Is it possible to use only the spine-related questions from the BASDAI questionnaire? Fatigue to be assessed in clinical practice, as it is not currently assessed as a single domain in any composite measure How nail assessment can be added or captured in existing measures How to deal with fibromyalgia, as it affects all of these tools
Importance of skin disease	If residual skin disease is allowed within a target, how does this affect the patient? In different populations, how do standard MDA and modifications requiring skin/joints compare? Validation of more feasible proxies for the PASI such as physician's global assessment \times body surface area
Potential modifications	CPDAI Can the CPDAI be adapted to include other modules? Can the DAPSA score be used for the joint portion? SPARCC to LEI conversion Nails What if you use the spine measures and not the BASDAI? Should the PASI be substituted with body surface area? Could this be simplified? Could other modules for the CPDAI be added (e.g., life impact)? DAPSA score The PCA cohort did not include patients with more severe skin disease—repeat PCA in a cohort with more skin disease Does skin pain factor into the pain VAS? Should global assessment be expanded to include skin and arthritis? What would a target that includes the DAPSA score plus skin or the DAPSA score plus skin and nails assessment look like, and how would it behave psychometrically? GRACE Can the GRACE be adapted to include body surface area? Can the PsAQoL be substituted with the PsAID in the GRACE? RAPID3 Can the HAQ be substituted with a skin assessment in the RAPID3? MDA Switch out the HAQ for the PsAID or other patient-reported outcomes Add impact on patient/PsAID Add nails, or nail VAS Body surface area target 1% (although 3% is acceptable)—should this be changed for VLDA?
Global assessment	Does the patient's global assessment capture the correct domains? What happens when the definitions of patient's global assessment are changed in different measures? Retrospective analysis of different approaches to carrying out global assessments
HAQ	How are composite scores affected when the HAQ is excluded, and how does this change the psychometric properties of the other outcomes? If physical outcomes are necessary to include in composite measures, is the HAQ the most appropriate measure? Can a new outcome measure for physical function be used instead of the HAQ? Can the HAQ be substituted with the PsAID? Can the HAQ be excluded from MDA, and what difference does this make?
Comparing remission	What prevents a person from achieving MDA/VLDA? What prevents a person from achieving DAPSA score remission/LDA? Among the DAPSA score remission group, what is preventing someone from achieving VLDA?

* 3VAS score = average of scores on 3 visual analog scales (patient's assessment of skin disease, patient's global assessment of disease activity, and physician's global assessment of disease activity); CPDAI = composite psoriatic disease activity index; GRACE = Group for Research and Assessment of Psoriasis and Psoriatic Arthritis composite index; PASDAS = psoriatic arthritis disease activity score; FDA = Food and Drug Administration; BASDAI = Bath Ankylosing Spondylitis Disease Activity Index; MDA = minimal disease activity; PASI = Psoriasis Area and Severity Index; DAPSA score = disease activity in psoriatic arthritis score; SPARCC = Spondyloarthritis Research Consortium of Canada; LEI = Leeds enthesitis index; PCA = principal components analysis; VAS = visual analog scale; PsAQoL = Psoriatic Arthritis Quality of Life questionnaire; PsAID = PsA Impact of Disease questionnaire; RAPID3 = Routine Assessment of Patient Index Data 3; HAQ = Health Assessment Questionnaire; VLDA = very low disease activity.

even in established disease it frequently shows change and can be useful to measure.”

The majority of health care professionals (92%) supported the recommendation that the conceptual target should be remission or, alternatively, MDA/LDA. Some pointed out that there is not yet evidence for additional benefits of remission over MDA, and that there may be a risk of increased treatment burden. Ninety-two percent supported the recommendation that the target should include musculoskeletal and skin disease, and 90% supported the inclusion of HRQoL as well. Ninety percent supported the recommendation of VLDA and/or MDA as the treatment target to be used.

Patient survey. A total of 64 patients responded to the postmeeting survey. The majority (72%) supported the recommendation that the target should encompass musculoskeletal disease, skin disease, and HRQoL. They also specifically mentioned fatigue, enthesitis, and physical function as key domains. The vast majority (90%) supported the concept of remission or, alternatively, LDA as a target and the recommendation for the use of VLDA/MDA (77%).

Research agenda

Throughout the meeting, items for the research agenda were identified and noted (Table 4). While a significant amount of data are available for the composites following recent research, as identified by the systematic literature review, there is still much to understand about these measures. Many composite measures were developed without substantial patient involvement, and this should be addressed in future research. Recent research has highlighted the fact that concomitant fibromyalgia affects all disease outcome measures, and this must be considered. A variety of validation data are missing for specific measures. In particular, there has been very little analysis of the 3VAS score, and this needs considerably more validation. For some of the composite measures, additional data are particularly required on the validity of the cut points as potential targets, such as those for the PASDAS and CPDAI.

A number of research agenda items related to less well-studied domains including axial disease, fatigue, and nail disease. While many measures include a patient’s global assessment of disease activity, much of the language used in these composites would benefit from further analysis and standardization. A number of potential modifications were also suggested for the existing composites. For the multidomain measures, the majority of modifications were related to simplification (e.g., body surface area or physician’s global assessment \times body surface area substituted for the PASI) or

substitution of HRQoL or physical function measures. There was interest in studying the DAPSA score alongside a skin measure, particularly when considering it as a target. Particularly for potential targets, additional data directly comparing measures and their concordance/discordance will be valuable for understanding them further.

Summary

Within the OMERACT framework for developing a core outcome measurement set for PsA (2), a consensus meeting is reported that established current practice using physician and patient surveys, discussed current systematic literature reviews to establish evidence, debated the advantages and disadvantages of the different measures, and recommended the use of composite measures and clinical targets. While a single composite measure was not chosen, a research agenda was established to aid in this. For targets, there was agreement on the conceptual definition of the target (remission or, alternatively, LDA/MDA), domains that should be considered (musculoskeletal disease, skin disease, and HRQoL), and a proposed target of VLDA or MDA for current practice.

ACKNOWLEDGMENT

We acknowledge the invaluable input and support of Dr. Anne-Maree Keenan (University of Leeds, Leeds, UK), who was the independent chair of the consensus meeting in February 2017.

AUTHOR CONTRIBUTIONS

All authors were involved in drafting the article or revising it critically for important intellectual content, and all authors approved the final version to be published. Dr. Helliwell had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study conception and design. Coates, FitzGerald, Merola, Smolen, van Mens, de Wit, Helliwell.

Acquisition of data. Coates, de Wit, Helliwell.

Analysis and interpretation of data. Coates, FitzGerald, Merola, Smolen, van Mens, Bertheussen, Boehncke, Callis Duffin, Campbell, de Wit, Gladman, Gottlieb, James, Kavanaugh, Kristensen, Kvien, Luger, McHugh, Mease, Nash, Ogdie, Rosen, Strand, Tillett, Veale, Helliwell.

ROLE OF THE STUDY SPONSORS

This activity was made possible by unrestricted educational grants from AbbVie, Eli Lilly and Company, Pfizer, and Novartis on GRAPPA. No company or company representative had any influence on the planning, content, or output of the meeting. Company representatives were permitted as nonparticipating observers at the meeting; however, no company or company representative received the manuscript before submission. AbbVie, Eli Lilly and Company, Pfizer, and Novartis had no role

in the study design or in the collection, analysis, or interpretation of the data, the writing of the manuscript, or the decision to submit the manuscript for publication. Publication of this article was not contingent upon approval by AbbVie, Eli Lilly and Company, Pfizer, and Novartis.

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