

**Outcomes of the 2019 GRAPPA Workshop on Continuous Composite Indices
for the Assessment of Psoriatic Arthritis and Membership-Recommended
Next Steps**

William Tillett, Neil McHugh, Ana-Maria Orbai, Alexis Ogdie, Ying Ying Leung,
Laura C. Coates, Philip Mease, Dafna D. Gladman, Mel Brooke, Jon Packham,
Denis O'Sullivan, Oliver FitzGerald, Philip S. Helliwell

ABSTRACT: *Background.* Improving the assessment of psoriatic arthritis (PsA) is a key purpose of the Group for Research and Assessment of Psoriasis and PsA (GRAPPA). Herein, we report the proceedings of the GRAPPA composites workshop at the 2019 GRAPPA annual meeting and the membership's recommended next steps.

Methods. A review of continuous composite measures was conducted in an introductory workshop, followed by 10 breakout group sessions and a final plenary session for feedback and voting.

Results. Participants included 154 members: 87 rheumatologists, 18 dermatologists, 2 rheumatologist/dermatologists, 12 patient research partners (PRPs), 14 academics, 1 methodologist, and 20 industry members. Of voting members, 88.8% agreed a need exists for a continuous composite measure for routine practice, but only 62% were currently using a composite measure and, of these, 27% were using the Disease Activity Score (DAS) 28, which is not a PsA-specific measure; 20% were

using a PsA-specific measure such as PsA DAS (PASDAS), Composite Psoriatic Disease Activity Index (CPDAI), or Disease Activity Index for PsA (DAPSA).

Members felt the existing measures were not feasible in their current forms (CPDAI (84%), PASDAS (82%), and DAPSA (47%)) and that modification should be tested. The majority (76%) agreed that disease impact should be measured separately from disease activity.

Conclusion. The GRAPPA membership supports the need for a continuous composite measure of disease activity for use in routine clinical care, the separate measurement of disease impact and activity, and the testing of modifications to candidate instruments rather than the development of new measures.

Key Indexing Terms: Psoriatic Arthritis, Outcome Measurement, Composite Measures, GRAPPA

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Author Information: W Tillett, BSc, MB ChB, PhD, MRCP, [ORCID: 0000-0001-7531-4125], Consultant Rheumatologist, Senior Lecturer, Royal National Hospital for Rheumatic Diseases, University of Bath, Bath, United Kingdom, w.tillett@nhs.net; Neil McHugh, MBChB, MD, FRCP, FRCPath, [ORCID: 0000-0003-2765-658X], Department of Pharmacy and Pharmacology, University of Bath, Bath, United Kingdom, N.J.McHugh@bath.ac.uk; A-M Orbai, MD, MHS, [ORCID: 0000-0001-8644-8567], Assistant Professor of Medicine, Director Psoriatic Arthritis Program, Division of Rheumatology, Johns Hopkins University School of Medicine, Baltimore,

Maryland, USA, aorbai1@jhmi.edu; A Ogdie, MD, MSCE, [ORCID: 0000-0002-4639-0775], Associate Professor of Medicine and Epidemiology, Perelman School of Medicine, University of Pennsylvania, Philadelphia, Pennsylvania, USA, alogdie@penmedicine.upenn.edu; YY Leung, MB ChB, MD, [ORCID: 0000-0001-8492-6342], Associate Professor, Duke-NUS Medical School, Singapore, Department of Rheumatology and Immunology, Singapore General Hospital, Singapore, katyccc@hotmail.com; LC Coates, MB ChB, PhD, [ORCID: 0000-0002-4756-663X], National Institute for Health Research Clinician Scientist, Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, United Kingdom, laura.coates@ndorms.ox.ac.uk; PJ Mease, MD, [ORCID: 0000-0002-6620-0457], Rheumatology Research, Swedish Medical Center/Providence St. Joseph Health and University of Washington School of Medicine, Seattle, Washington, USA, pmease@philipmease.com; DD Gladman, MD, FRCPC, [ORCID: 0000-0002-9074-0592], Professor of Medicine, University of Toronto, Senior Scientist, Krembil Research Institute, Director, Psoriatic Arthritis Program, University Health Network, Toronto Western Hospital, Toronto, Ontario, Canada, dafna.gladman@utoronto.ca; Mel Brooke, [ORCID: None], Patient Research Partner, Royal National Hospital for Rheumatic Diseases, Bath, United Kingdom, brookem@btinternet.com; Jon Packham DM, FRCP, [ORCID: 0000-0001-5531-1680], Division of Epidemiology and Public Health, University of Nottingham, Nottingham, United Kingdom, Jon.packham@mpft.nhs.uk; Denis O'Sullivan, BE, [ORCID: 0000-0002-6607-6070], Patient Research Partner, Rheumatic and Musculoskeletal Disease Unit, Our Lady's Hospice and Care Services, Dublin, Ireland, denis_osullivan@ymail.com; O FitzGerald, MD, FRCPI, FRCP(UK), [ORCID: 0000-0002-6607-6070], Consultant Rheumatologist and Newman Clinical Research

Professor, Conway Institute for Biomolecular Research, University College Dublin,
Dublin, Ireland, oliver.fitzgerald@ucd.ie; PS Helliwell, MD, PhD, [ORCID: 0000-0002-
4155-9105], Chapel Allerton Hospital, Harehills Lane, Leeds, United Kingdom,
p.helliwell@leeds.ac.uk

Corresponding Author: William Tillett, Royal National Hospital for Rheumatic
Diseases, Coombe Park, Bath, BA13NG United Kingdom; phone 01225 428331; e-
mail w.tillett@nhs.net

Running Footline: Psoriatic Arthritis Composite Indices

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Background

Improving the assessment of psoriatic arthritis (PsA) is one of the key purposes of the Group for Research and Assessment of Psoriasis and PsA (GRAPPA) and was identified as a priority at the 2016 GRAPPA leadership retreat.⁽¹⁾ The development of continuous, as distinct from categorical, composite measures of disease activity that are specific to PsA has been an area of research focus. A number of different continuous composite measures have been developed for use in Rheumatoid Arthritis (RA) such as the Clinical Disease ACTivity Index (CDAI), Simplified Disease ACTivity Index (SDAI), and Disease Activity Score 28 (DAS 28). It is recognised that considerable advances have been made in the care of patients with RA with the development and widespread adoption of a single outcome measure. The DAS28 is an instrument with well-recognised, clinically recognisable thresholds of remission, as well as low, moderate, and high disease activity. A continuous measure, such as the DAS28, allows the practising clinician and patient to assess grades of response and to readily track change over time. By comparing data from different trials, cohorts and registries become much more accessible for clinicians and payers with the DAS28 as a universally recognised metric. This facilitates the adoption of new research findings, such as treat-to-target, into routine practice. Although the DAS28 has been shown to be discriminative and responsive in PsA,⁽²⁾ it has been psychometrically surpassed in that disease by more PsA-specific measures reviewed below.

A number of composite measures of disease activity have been developed for PsA, but it has been challenging to achieve consensus on which instrument to take forward.^(3, 4) The following questions were asked at the 2019 GRAPPA composites workshop:

1. Is there a need for a continuous composite measure?
2. What are the barriers to wider adoption of existing measures?
3. How does the PsA Impact of Disease (PsAID) influence the use of composite activity measures in PsA?
4. Can existing barriers be overcome by testing modifications to existing instruments?

Here, we report the proceedings of the GRAPPA composites workshop at the 2019 GRAPPA annual meeting and the membership's recommendations for next steps.

Patient Research Partner (PRP) Briefing

Background information on continuous composite measures was developed in lay terms for the GRAPPA PRP members and given to PRPs prior to the 2019 GRAPPA annual meeting.

Workshop

A 2-hour composite measures workshop was held. The workshop opened with an introductory session that covered the aims, objectives, background, and relevant data of the composite measures field. A question and answer session was then held, followed by a 45-minute breakout session that included 10 breakout groups to discuss and gain an in-depth understanding of the GRAPPA membership's views on continuous composite measures for routine care, challenges to wider adoption of composite measures, and next steps. Each group was led by an expert in the field who was identified from the GRAPPA-Outcome Measures in Rheumatology (OMERACT) working group.⁽⁵⁾ The groups were asked to discuss the topic in 2 stages. During the first stage, all groups discussed:

1. Is there a need for a continuous composite measure of disease activity

in PsA?

2. Should modified versions of existing composite measures be tested?
3. Should shortened versions of existing composite measures be tested?
4. Is it desirable to measure impact (PSAID) separately from activity?

During the second stage, individual groups were asked to discuss a specific composite (3 groups discussed the Disease Activity Index for PsA (DAPSA), 3 discussed the PsA Disease Activity Score (PASDAS), and 4 discussed the Composite Psoriatic Disease Activity Index (CPDAI)):

1. Is it feasible?
2. What modifications could be tested?
3. What options to shorten could be tested?

Each breakout group had PRP, rheumatology, dermatology, and industry representatives. The breakout group leaders provided key verbal feedback to the whole membership in the plenary and a written summary for this report. Voting then took place for the attending membership. Additional voting questions were added to address questions that arose from the breakout groups and plenary discussions.

Plenary Presentations

The need for a continuous composite measure of disease activity. Dr. William Tillett opened the plenary presentations with a review of the need for a continuous composite measure for routine clinical use in PsA, how the PSAID measure influences the debate, the historic lack of patient involvement, and the development of a dataset to test modifications to existing candidate measures.

It is well known that PsA is a heterogeneous disease that may affect an individual in multiple ways, including joints, skin, entheses, spine, systemic feelings of fatigue, and associated comorbidities. It is equally recognised that PsA is

generally not as destructive as RA, but has similar impacts on physical functioning, ability to work, and health-related quality of life due to its multiple manifestations. Thus, there is a need for a composite measure to better quantify wider manifestations of disease activity that would otherwise be underrepresented if clinicians and payers only take into account peripheral articular disease.

The pitfalls of current composite measures in PsA. Dr. Tillett highlighted a systematic literature review that identified very little patient involvement in the development of PsA outcome measures, including composites.(6) The lack of patient involvement, and therefore the “lived experience” of PsA, may result in the omission of domains of disease that are important to patients, which limits the face validity of existing composites.(6) Other challenges to wider adoption of composites include the time-consuming nature of multiple assessments, complex calculations, proprietary/expensive measures, and philosophical concerns related to combining outcomes into a single measure.

Addressing patient involvement. Dr. Tillett reviewed the following program of work that addresses the lack of patient involvement in the development of composite measures and the ASSESS study that tests modifications as part of the United Kingdom (UK) PROMPT programme (early detection to imPRove OutCoMe in people with undiagnosed Psoriatic arthriTis) (RP-PG-1212-20007).

A qualitative study was undertaken to identify outcomes that are important to patients. Eight focus groups at 5 hospitals across the UK, including 41 patients, with a range of disease phenotype, disease duration, age, and gender, were analysed using thematic analysis.(7) Over 60 outcomes were identified and grouped into 4 themes: alleviation of symptoms,

reduction of disease impact, improved prognosis, and minimisation of treatment harm.(7) The outcomes were then ranked using a nominal group technique and mapped to existing composite measures, the OMERACT core domain set, and the PsAID questionnaire. Pain and fatigue were identified as the outcomes that were most important to patients that were not well represented in existing composite measures.(8)

A conceptual framework for measuring disease impact and disease activity. Dr. Tillett then reviewed the concept of disease impact and how the development and rapid adoption of the PsAID instrument has influenced the field of composite measures of disease activity.

The concept of disease impact is defined by Sanderson et al. as a culmination of disease severity, self-management, and importance.(9) The PsAID instrument has been developed as a PsA-specific measure of disease impact that OMERACT has validated and endorsed as a measure of health-related quality of life.(10-12) Dr. Tillett presented a conceptual framework for the modification of composite measures of disease activity that proposed whether it was theoretically desirable for an activity measure to be responsive and not influenced by irreversible damage or external factors that are part of measuring impact (such as self-management and importance to the individual).(13)

A new dataset to test modification of existing composite measures. Dr. Tillett concluded with a review of the ASSESS study undertaken to provide a dataset to test modifications to composite measures. Study participants included 141 people with PsA who fulfilled the CIASSification for PsA (CASPAR) criteria who were recruited from 5 centres across the UK and assessed at baseline, 3 months, and 6 months, with a wide range of clinical and patient-reported measures to allow for the

calculation of composite measures. Thirty patients with stable disease were re-assessed after 1 week. Participants were divided into those who required treatment change (as a surrogate for active disease) and those with stable disease (as a surrogate for inactive disease). The presence of comorbid fibromyalgia was recorded for planned secondary analyses. The composite measures that can be derived from the ASSESS study were presented to GRAPPA members, together with their potential modifications.

CPDAI. Professor FitzGerald reviewed the CPDAI.(14) The CPDAI was originally conceived to capture the first OMERACT core set and includes assessment of peripheral arthritis (66/68 swollen and tender joint count and Health Assessment Questionnaire (HAQ)), skin psoriasis (Psoriasis Area Severity Index (PASI) and Dermatology Life Quality Index (DLQI), enthesitis (Leeds Enthesitis Score (LEI) and HAQ), dactylitis (tender dactylitis count and HAQ), and axial disease (Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) and Ankylosing Spondylitis Quality of Life Index (ASQoL)). Each domain is scored as 0 (none), 1 (mild), 2 (moderate), or 3 (severe).(14) The resulting total score ranges from 0 (no disease) to 15 (active disease). The CPDAI has been validated in randomized controlled trial (RCT) datasets and distinguishes active treatment from placebo.(15) CPDAI has disease activity cut offs for high, moderate, and low disease activity, as well as remission; CPDAI has been shown consistently to be more sensitive to change than DAPSA but not as good as PASDAS.(3)

Professor FitzGerald reviewed why there has not been wider adoption of the CPDAI to date. Reasons may include (1) the absence of direct representation of outcomes important to patients (pain and fatigue); (2) the use of quality of life measures that are proprietary (ASQoL); (3) the use of

HAQ that could represent damage/impact rather than activity; (4) the inclusion of the PASI to measure skin disease, which is time-consuming for clinicians; and (5) the use of the BASDAI as a measure of spinal disease, as BASDAI may reflect peripheral joint disease in patients with PsA.

Professor FitzGerald reviewed previous modifications of the CPDAI and noted that as a “modular” measure, the CPDAI is amenable to being adapted. The most frequent modification is the omission of the spinal domain, which results in a score of 0-12. Testing the addition of patient global and pain in the GRAppa Composite Exercise (GRACE) dataset did not improve the ability of the CPDAI to detect need for treatment change (authors own data, unpublished), but their inclusion may improve face validity. Other potential modifications could include (1) the addition of a patient-reported outcome measure (PROM) domain that includes patient global, fatigue, or pain visual analogue scale (VAS); (2) the use of a short version for feasibility; (3) the substitution of the quality of life measures with the PSAID; (4) the substitution of PASI with VAS scores/body surface area (BSA); and (5) the use of DAPSA as the measure of peripheral articular disease within the CPDAI. All such modifications could be tested in data obtained in the ASSESS study.

PASDAS. Dr. Helliwell presented a review of the PASDAS, an 8 item score comprised of (1) 66 swollen joint count, (2) 68 tender joint counts, (3) tender dactylitis count, (4) physician global VAS, (5) patient global VAS, (6) C-reactive protein (CRP), (7) Leeds Enthesitis Index, and (8) physical function component of the SF-36 or SF-12.(16) The PASDAS score ranges between 0 (no disease) and 10 (severe disease) based on a weighted formula and has validated cut offs for high, moderate, and low disease activity, as well as near remission. As opposed to the CPDAI, which was developed to be comprehensive and cover all clinical domains of

disease, the PASDAS was developed as a composite measure of disease activity using a data-driven approach, including only outcomes that improve ability to detect change. The PASDAS has been shown to perform better than purely articular measures in multiple datasets and predicts radiographic progression.(15, 17) Dr. Helliwell reviewed what is desirable from a composite measure of disease activity (for routine care) perspective, including the need to be feasible, meaningful, and responsive, as well as the need to capture all disease manifestations. When considering why the PASDAS has not been adopted more widely, he explained that the measure is perceived to be complicated, time-consuming (as it requires multiple clinical assessments and a laboratory test), and difficult to calculate. Modifications to the PASDAS could be tested, including the addition of pain, fatigue, or different measures of physical function. A self-assessment PASDAS is currently under evaluation and is focused on arthritis, enthesitis, dactylitis, and psoriasis skin VAS scores.

DAPSA. Dr. Tillett reviewed the DAPSA instrument, which is comprised of the 66/68 swollen and tender joint count, joint pain VAS, patient global VAS, and CRP.(18) The clinical DAPSA (cDAPSA), which does not include CRP, is also available for use in order to improve feasibility. The DAPSA has been validated in RCT datasets, has established cut points for remission (≤ 4), as well as low (>4 and ≤ 14), moderate (>14 and ≤ 28), and high disease activity states (>28). (19) The DAPSA correlates well with physical function and structural damage in RCT datasets.(20) The DAPSA is a measure of peripheral joint disease in PsA rather than a comprehensive measure of disease, as it does not include measures of enthesitis, psoriasis, dactylitis, or axial disease. The DAPSA also does not include measures of physical function, quality of life, or fatigue. Potential modifications should be approached with caution as the

strength of the DAPSA lies in its feasibility and its focus on 1 aspect of disease, joint manifestations. Potential modifications to DAPSA could include additional musculoskeletal manifestations (enthesitis, dactylitis, axial disease), skin disease, or testing the DAPSA as a subcomponent of the CPDAI.

Breakout Group Summary

The GRAPPA composites workshop participants were divided into 10 breakout groups. The results of the groups discussing the CPDAI, PASDAS, and DAPSA are detailed in Table 1, Table 2, and Table 3, respectively. The composition of GRAPPA members who participated in the plenary voting, as well as the plenary voting results are reported in Table 4.

Is there a need for a continuous composite measure of disease activity in PsA?

The majority of members agreed that there is a need for a continuous composite measure for routine practice (88.8%), but nearly two thirds of the voting membership (65%) were either using the DAS28 (26.8%) or no measure at all (38%). Only a minority were using a PsA-specific measure such as the DAPSA (12.7%), PASDAS (5.2%), and CPDAI (3%). The remainder (14.2%) were using other measures. All 10 breakout groups agreed that a composite measure of disease activity was needed for routine clinical practice, consensus on a single measure was desirable, and impact and activity should be measured separately.

Should modified versions of existing composite measures be tested? The majority of members supported the testing of modifications to both the CPDAI (71.6%) and the PASDAS (81.8%) to address barriers to wider adoption (Table 4). Opinions were split on the testing of modifications to the DAPSA with 52% voting to leave the DAPSA unchanged and 48% voting to test modifications (Table 4). There was a minority view expressed that, instead of modifying existing composite measures, a

new measure should be developed based on the updated 2016 core domain set with an improved conceptual framework. It was suggested that the 3 VAS (3VAS) score and Routine Assessment of Patient Index Data 3 (RAPID3) should be considered as other options for a continuous composite measure of disease activity. The 3VAS and RAPID3 were not included in this present workshop because of discussions at a previous international consensus meeting where there have been reservations about taking forward measures that do not include physical examination/clinical assessment.⁽³⁾ It was suggested that either the 3VAS or RAPID3 could be tested as a short version of a more comprehensive composite.

Should shortened versions of an existing composite measure be tested? Members felt the existing measures, CPDAI (84%), PASDAS (82%), and DAPSA (47%), were not feasible in their current forms. Members agreed that modifications and shortenings should be tested (Table 4), with most supporting the testing of more prominent inclusion of pain and more feasible methods of psoriasis assessment. There were no strong differences between dermatologist and rheumatologist voting, with the exception of the PASI. As a group, 79% voted that the PASI was not feasible in routine practice. A breakdown of those voting on the PASI indicated that 6 of 18 (33%) dermatologists voted the PASI to be feasible, but only 15 of 86 (17%) rheumatologists voted the PASI to be feasible. The challenge of performing the 66/68 joint count in clinical practice was raised in a DAPSA breakout group and discussed in the plenary during feedback. It was recognized that the 66/68 joint count was necessary to adequately assess joint disease and the challenge of feasibility related to the joint count applied to the CPDAI, PASDAS, and DAPSA. Another limitation of the DAPSA discussed in the breakout group was the requirement for a CRP to complete the DAPSA (not required in the cDAPSA) as the

CRP is frequently not available at the time of the visit. However, this differed by country and by practice. There was debate in each group about striking the balance between shortening a composite measure to make it feasible in clinical practice versus oversimplifying a measure that then fails to achieve its purpose of being a more global assessment of disease.

Is it desirable to measure impact (PSAID) separately from activity? There was strong agreement (76%) that impact should be measured separately from activity in the voting, and the same message was communicated in the breakout groups' feedback.

Summary

In this meeting report from the 2019 GRAPPA composites workshop, we detail the rationale for a continuous composite measure of disease activity for routine care in PsA and the challenges to wider adoption. In addition, we detail the barriers to uptake of the CPDAI, PASDAS, and DAPSA; the disadvantages of each measure; the potential modifications to test in the ASSESS study dataset; and the GRAPPA membership's views on how to take each measure forward.

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