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Consensus of the definitions of the OMERACT glucocorticoid impact core domain set for people with rheumatic and musculoskeletal diseases

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ABSTRACT

Background: The Outcome Measures in Rheumatology (OMERACT) Glucocorticoid (GC) Impact Working Group has been working to develop a core domain set to measure the impact of GCs on patients living with rheumatic and musculoskeletal diseases. The mandatory domains previously identified for inclusion in all clinical trials measuring the GC effects include infection, bone fragility, mood disturbance, hypertension, diabetes, weight, fatigue, and mortality. Before progressing to instrument selection, the Working Group sought to establish precise definitions of all mandatory domains within the core domain set.

Methods: OMERACT methodology was applied with the use of evidence and consensus-based decision making of all stakeholder groups (patient research partners, health care professionals, clinician researchers, industry members and methodologists) to develop detailed definitions for the broad domain, target domain and domain components, taking into consideration sources of variability that could affect measurement of the domain. The working group synthesized prior qualitative studies, quantitative work, and results from Delphi rounds, to develop a rich definition of 'what' is to be measured.

Results: Between 2021 and 2023, the OMERACT Working Group on GC Impact conducted virtual meetings to establish domain definitions. First, we mapped each domain onto an OMERACT Core Area. All domains were primarily represented within the Pathophysiological Manifestations Core Area, except from Fatigue which was primarily Life Impact and Weight which spanned both Core Areas. Sources of variability included cultural factors, age, gender, education level, socioeconomic status, personal experiences, emotional state, and language barriers. The domain definitions will form the foundation for instrument selection and the initial step of domain / concept match and content validity in the OMERACT pillar of 'truth' before moving on to feasibility and discrimination.

Conclusion: The OMERACT GC Impact Working Group has developed and agreed upon detailed domain definitions for core domains. Future steps of the working group are to select instruments and develop the core outcome

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measurement set for clinical trials measuring the impact of GC on patients with rheumatic and musculoskeletal diseases.

Background

Glucocorticoids (GC) are potent anti-inflammatory agents which play an integral role in the early and effective management of many rheumatic and musculoskeletal diseases (RMDs) [1]. However, treatment-related morbidity may result in numerous adverse effects that are concerning to both patients and clinicians [2]. Although these adverse effects are well documented, the impact on individual patients is difficult to quantify and the need for a standardized instrument to measure the effect of GC therapy has been recognized [1,3,4]. Clinical trials comparing novel steroid-sparing agents against conventional therapy continue to expand and reliable measurement of GC toxicity remains a critical clinical issue. As such, a validated outcome measure which captures the patient's perspective of symptoms related to the use of glucocorticoids has become increasingly important. Existing instruments, such as the Glucocorticoid Toxicity Index (GTI) [5] measure the physiological effects of systemic GC therapy, but do not incorporate the patient perspective or patient reported outcome measures (PROMs).

Outcome Measures in Rheumatology (OMERACT) has sought to establish 'Core Outcome Sets', comprised of a minimum set of outcomes that should be measured in all clinical trials to achieve standardization and ensure validity of outcomes in trials and thus enable comparison across these trials [6]. This process is achieved through an evidence driven, iterative consensus process which can be divided into two phases. The first phase involves development of a "Core Domain Set" (i.e., "what to measure"). The second phase seeks to establish a "Core Outcome Measurement Set" (i.e., "how to measure") [7].

The OMERACT Working Group on GC Impact (https://omeract.org/working-groups/glucocorticoids/) has developed a core domain set to measure GC impact [8]. This was derived from prior work including systematic literature reviews and qualitative analysis of interviews and surveys of patients with RMDs in order to further understand their perception of GC therapy [9–17]. Based on that research, a modified Delphi exercise was undertaken to condense and prioritize outcomes related to GC use that were important to both patients and clinicians [16]. Mandatory domains to be included in any clinical trial where the effects of glucocorticoids are measured included infection, bone fragility, mood disturbance, hypertension, diabetes mellitus, weight, fatigue, and death. The following domains were considered important but optional: osteonecrosis, eye problems, appearance, and sleep disturbance (Fig. 1) [18].

Before progressing to instrument selection, and following updated guidance in the OMERACT Handbook [7,19], the GC Impact Working Group sought to establish detailed definitions for all mandatory domains in their core domain set. These detailed definitions will provide the foundation for instrument selection and contribute towards the group's fundamental aim of developing a core outcome set to be included in any clinical trial where the effects of GCs are measured.

Methods

The OMERACT GC Impact working group is comprised of health care professionals, clinician researchers, patient research partners, industry members, and methodologists from the USA, UK, and Australia. Over a 2-year period, from 2021 to 2023, the OMERACT GC Impact working group conducted monthly virtual meetings to establish domain definitions. OMERACT methodology was applied with the use of evidence- and consensus- based decision making of all stakeholder groups to develop detailed definitions for each target domain, taking into consideration sources of variability that could impact the score obtained on a given outcome measurement instrument (e.g., variability due to machine or reader). The group utilized a domain definition template that was current at the time of writing [18]. This template facilitates application of a layered approach, so that the following components may be considered: core area (i.e. pathophysiological vs life impact) [20], broad domain, target domain, domain components (i.e. components that are important for the instrument to capture), qualitative or literature support, and sources of variability (Fig. 2). All prior qualitative and quantitative work, as well as review of comments from the Delphi round, were considered so that the working group was able to develop a rich definition of 'what' is to be measured [18]. To finalize domain definitions, a formal vote was undertaken by all working group members to establish consensus.

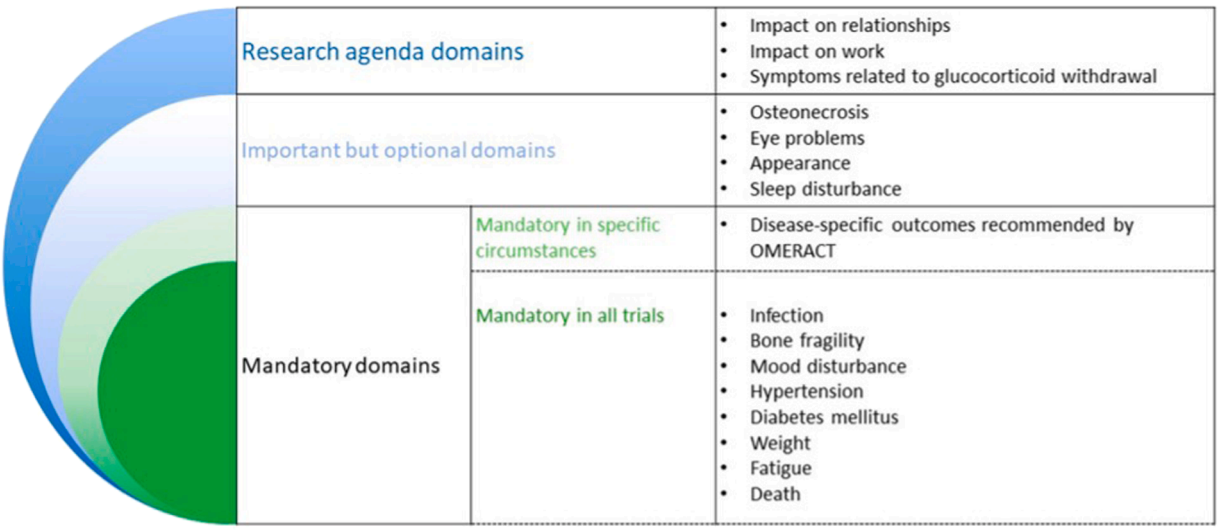

Fig. 1. OMERACT Glucocorticoid impact core domain set [18].

Results

Domain definitions

Domain definitions were developed from 2021 to 2023 during monthly virtual meetings, for the eight domains identified through the Delphi process: infection, bone fragility, mood disturbance, hypertension, diabetes mellitus, weight, fatigue, and death.

The development of the core outcome set which measures the impact of glucocorticoids is unique when compared to the work of other OMERACT working groups, where the focus is typically on a disease process or diagnostic tool. As such, the OMERACT GC working group faced some unique challenges when considering the various applications of the outcome set and therefore the core area for each domain. To complement the conceptual framework of the OMERACT Onion, with its many layers, the group developed the concept of numerous segments clustering together, enabling the group to conceptualize and re-prioritize how each domain was considered mapping it primarily to the Pathophysiological Manifestations Core Area, Life Impact Core Area, or both. This allowed the working group to re-align discussion around the precise definition of the domains and their sources of variability.

The primary Core Area identified for each domain was Pathophysiological, with the exception of weight, which mapped to both Pathophysiological and Life Impact, and fatigue, which mapped to primarily Life Impact. Tables 1 and 2 provide a summary of the broad domain, target domains, and detailed definition for each domain, divided into pathophysiological and life impact as applicable.

Sources of variability and measurement of contextual factors

In medical research, clinical instruments are often used to assess various aspects of health, such as physical or psychosocial factors. However, sources of variability, otherwise known as measurement-affecting contextual factors, have the potential to influence the performance of an outcome measure. Three subgroups are recognized within the OMERACT framework, including personal factors (e.g., age, sex, race, and socioeconomic status), disease-related factors (e.g.. disease duration and disease severity), and environmental factors (e.g.. place of residence and healthcare system) [36]. Numerous measurement-affecting contextual factors were identified by the working group, most of which fell under the umbrella of personal or environmental factors. While some contextual factors, such as age or sex, might result in true biological differences in response to GCs, other contextual factors may result from differences in perception, equipment, measurement techniques, or medical practices.

Cultural factors can significantly impact health-related assessments [37]. Different cultures have unique beliefs, attitudes, and values that can influence how individuals perceive and report their health status [38]. For instance, cultural norms around expressing pain or discomfort, discussing mental health issues, or interpreting symptoms can vary greatly. Factors such as age, gender, education level, socioeconomic status, and personal experiences can influence how individuals respond to assessment questions or tasks [39] and may also affect biological response to GCs. Emotional states, mood, stress levels, social support, and self-perception can impact how individuals perceive and report their health status [40]. Language barriers or differences in communication styles can affect the validity and reliability of health assessments [41], as can differences in medical practice.

Discussion

The domain definitions agreed upon through this consensus-based decision-making process will form the foundation for instrument selection and the initial step of domain / concept match and content validity in the OMERACT pillar of 'truth' before moving on to feasibility and discrimination. During the next step of instrument selection, measurement-affecting contextual factors will be evaluated and evidence gathered on how they affect instrument measurement properties. To minimize the impact of these sources of variability, researchers should employ rigorous instrument development and validation procedures. This includes pilot testing the instrument in diverse populations, considering cultural and linguistic factors, addressing potential biases, and conducting psychometric analyses to ensure the reliability and validity of the instrument. Other sources of variability for specific domains, if present, would be highlighted separately. Future plans include further collaboration with other OMERACT groups working on projects where there has been significant overlap in the domains identified such as fatigue and sleep. These are common problems encountered by patients that may be difficult to measure, so unified domain definitions will facilitate comparability of results across trials.

This project has several strengths. First, data triangulation was utilized to develop the domain definitions, including prior qualitative studies, quantitative work, and results from Delphi-type exercises. Review of qualitative literature and salient quotes from the group's prior work helped provide a rich understanding of the patient perspective for each domain. Further, our patient research partners played an essential

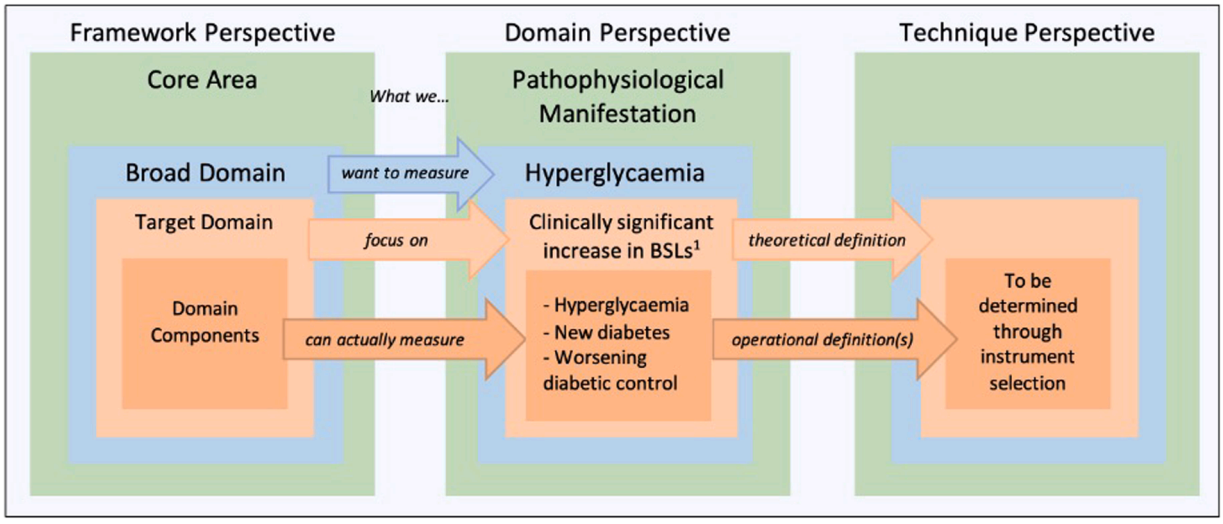

Fig. 2. The layered definition approach that provides a detailed definition of the domain and the elements of that domain that should be found in a suitable instrument using that technique. Example of mandatory domain, Hyperglycemia.[1] BSLs – Blood Sugar Levels.

Table 1
Core domain areas: Pathophysiological Manifestations of glucocorticoid therapy.

Core Area: Pathophysiological				
Broad Domain	Target Domain[1]	Domain Definition[1]	Qualitative support	Literature Support
Infection	Recurrent, atypical or serious infections	Diagnosis of recurrent, atypical or serious infection	*"I had a respiratory infection a lot; I seem subject to those. I would get skin infections, I had to be so careful not to break my skin and things"* [15] *"It does seem like I'm prone to picking things up at the minute … when I had a tooth out I had to go on to a long, quite a long period of antibiotics before and afterwards, just to make sure I was okay."* [17]	[21,22]
Bone Fragility	New or worsening bone fragility	Diagnosis new or worsening bone fragility	*"Having to take calcium pills – they're huge but you know why you're taking it"* *"I did bone density scan and they told me the bone density was getting lower and lower – but I never had a fracture or a break"* [15] *"Her bones basically crumbled within her. Osteoporosis I think was the cause of her death".* [17]	[23,24]
Hypertension	Clinically significant elevation in blood pressure	A new diagnosis of hypertension or worsening blood pressure after initiation of glucocorticoid.	*"By the time I got to five milligrams of Prednisolone, I, I didn't really need the blood pressure tablets anymore."* [17] *"I think I did end up with blood pressure … I don't know if that's a - but I never had that before I started taking it … So, then I went on blood pressure medication … So, that's just another - yeah, you start taking medications, and then you start taking medications because of the medications kind of thing"* [17]	[25,26]
Hyperglycemia	Clinically significant increase in blood glucose levels	New onset hyperglycemia New diagnosis diabetes mellitus Worsening control of existing diabetes mellitus, as evidenced by need to increase therapy or the development/ progression of diabetic complications.	*"I then became pre-diabetic as a result of the steroids"* [17] *"The psychological effects of those diseases are – how can I put it, um, quite scary, especially when you've experienced long spells of insomnia. And it really doesn't matter what you take or what you do, I'm not one for taking medication and that includes, you know, strong pain killers… or, um, night sedation of any kind. I used to go down the, er, you know, a nice cup of chocolate route at night because I think it might have helped, or it certainly was comforting, until I was pre-diabetic and then I discovered the sugar content of it of which I've now become so much more aware… as a result of all of this."* [17]	[27,28]
Weight	Weight and appetite changes	Change in weight Appetite and dietary	*"gained 12 kg due to markedly increased*	[30,31]

(*continued on next page*)

Table 1 (*continued*)

Core Area: Pathophysiological				
Broad Domain	Target Domain[1]	Domain Definition[1]	Qualitative support	Literature Support
		changes, including food preferences and eating patterns, (i.e., overwhelming need to eat, eating more frequently or binging)	*appetite."* [29] *"I gained way too much weight"* [29]	
Mood Disturbance	Mood disturbance	Anxiety – e.g., worry, stress, feeling overwhelmed Depression – e.g., sadness, hopelessness Anhedonia – e.g., avolition, apathy Lability – e.g., personality changes, irritability, impatience, anger Elevation – e.g., euphoria, hypomania, mania, psychosis	*"when my steroids are high… I'm taking, well for me say about 30 mg a day, I get a kind of a depression almost. And it's almost like-Well why should I bother getting up?"* [14] *"··in my personal life. Probably in my work life···I would find myself going into extremely dark holes. I'd start an argument, and go down an argument that I knew that was complete stupid argument, but couldn't back off of it, and then have to go… So all that was all part of, of, of when I got these flare-ups, and then the constant treatment of steroids"* [14]	[32,33]
Death *mandatory for all OMERACT core outcome sets	Increased mortality as an adverse effect of GC therapy.	Increased incidence of death in the context of GC treatment		[34,35]

Definitions abbreviated for brevity. GC - glucocorticoid.

role in interpreting the patient perspective data, and for developing and refining the definitions. Well-established OMERACT methodology using a layered approach was applied to ensure definitions were comprehensive. Consideration of sources of variability allowed the group to account for measurement-affecting contextual factors, which will be central to instrument selection. Finally, there was contribution from numerous stakeholder groups, including patient partners, industry members, psychologists, and clinicians, as well as regular input from OMERACT methodologists, to ensure robustness and validity of results. There are however limitations to this study. Virtual meetings included

Table 2
Core domain areas: Life Impact of glucocorticoid therapy.

Core Area: Life Impact				
Broad Domain	Target Domain[1]	Domain Definition[1]	Qualitative Support	Literature Support
Weight	Weight, appetite and weight gain	Personal perception of self and impact on mental health Influence on social participation and public social identity Financial implications such as weekly grocery bill and purchasing new clothes	*"I then [be] came a bit recluse… Because I was a bit embarrassed of my appearance, so I just stuck with my family and didn't really do much outside"* [29] *"it just is very frustrating because then you have to buy more clothes. I have a wardrobe right now that goes four different sizes as my weight goes up and down and up and down"* [29]	[30,31]
Fatigue	Fatigue is a common co-morbidity in patients treated with GC but despite being an important factor in quality of life is poorly understood in both cause and consequence.	Effect of fatigue on ADLs Effect of fatigue on social activity Effect of fatigue on independence and realisation of self/sick role Effect of fatigue on work life.	*"apart from feeling really awful was my mind just racing and being absolutely exhausted and not able to sleep because your mind doesn't stop, it's goes round and round and you're exhausted and you just end up waking up, if you got any shut-eye at all."* [17]	[11,13]

Definitions abbreviated for brevity. GC - glucocorticoid.

only members of the GC working group and the process was conducted exclusively online, thereby excluding individuals without internet access. Furthermore, all meetings were conducted in English. While there was representation of individuals from countries where English is not the official language, these group members comprised a marked minority and the generalizability of results to non-English speaking regions is therefore unknown.

Conclusion

In conclusion, the OMERACT GC Impact Working Group, through prior literature review and conduct of their own qualitative and survey studies, have agreed upon domain definitions for a core domain set. The next step of the working group is to select instruments and develop the core outcome set for inclusion in all clinical trials where the effects of GCs are measured.

CRediT authorship contribution statement

Suellen A. Lyne: Conceptualization, Data curation, Formal analysis, Investigation, Writing – original draft, Writing – review & editing. **Kevin Yip:** Conceptualization, Data curation, Formal analysis, Investigation,

Writing – original draft, Writing – review & editing. **Vasilis S. Vasiliou: . David A. Katz: . Pamela Richards:** Data curation, Formal analysis, Investigation, Validation. **Joanna Tieu:** Data curation, Formal analysis, Investigation, Resources, Writing – review & editing. **Rachel J Black:** Data curation, Formal analysis, Investigation, Resources, Writing – review & editing. **Susan Bridgewater:** Data curation, Formal analysis, Investigation, Validation. **Andriko Palmowski:** Data curation, Investigation, Writing – review & editing. **Dorcas Beaton:** Investigation, Methodology, Resources, Writing – review & editing. **Lara J Maxwell:** Formal analysis, Investigation, Methodology, Resources, Writing – review & editing. **Joanna C Robson:** Conceptualization, Formal analysis, Investigation, Writing – review & editing. **Sarah L Mackie:** Data curation, Formal analysis, Investigation, Resources, Writing – review & editing. **Susan M Goodman:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Supervision, Writing – review & editing. **Catherine L Hill:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Resources, Supervision, Writing – review & editing.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

DAK: is an employee, officer, and owner of Sparrow Pharmaceuticals.

JT: Unrestricted research grant from Vifor.

JCR: Consultancy and speaking fees Vifor. Unrestricted research grant from Vifor and Sanofi Ltd. Support to attend EULAR 2023 in person from Vifor.

SLM: Consultancy on behalf of her institution for Roche/Chugai, Sanofi, AbbVie, AstraZeneca, Pfizer; Investigator on clinical trials for Sanofi, GSK, Sparrow; speaking/lecturing on behalf of her institution for Roche/Chugai, Vifor, Pfizer, UCB, Novartis and AbbVie; chief investigator on STERLING-PMR trial, funded by NIHR; patron of the charity PMRGCAuk. No personal remuneration was received for any of the above activities. Support from Roche/Chugai to attend EULAR2019 in person and from Pfizer to attend ACR Convergence 2021 virtually. SLM is supported in part by the NIHR Leeds Biomedical Research Centre. The views expressed in this article are those of the authors and not necessarily those of the NIHR, the NIHR Leeds Biomedical Research Centre, the National Health Service or the UK Department of Health and Social Care.

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LJM: Paid staff member of OMERACT.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.semarthrit.2023.152338.

References

[1] Duru N, van der Goes MC, Jacobs JW, Andrews T, Boers M, Buttgereit F, et al. EULAR evidence-based and consensus-based recommendations on the management of medium to high-dose glucocorticoid therapy in rheumatic diseases. Ann Rheum Dis 2013;72(12):1905–13.

[2] van der Goes MC, Jacobs JW, Boers M, Andrews T, Blom-Bakkers MA, Buttgereit F, et al. Patient and rheumatologist perspectives on glucocorticoids: an exercise to improve the implementation of the European League Against Rheumatism (EULAR) recommendations on the management of systemic glucocorticoid therapy in rheumatic diseases. Ann Rheum Dis 2010;69(6):1015–21.

[3] Hoes JN, Jacobs JW, Boers M, Boumpas D, Buttgereit F, Caeyers N, et al. EULAR evidence-based recommendations on the management of systemic glucocorticoid therapy in rheumatic diseases. Ann Rheum Dis 2007;66(12):1560–7.

[4] van der Goes MC, Jacobs JW, Boers M, Andrews T, Blom-Bakkers MA, Buttgereit F, et al. Monitoring adverse events of low-dose glucocorticoid therapy: EULAR recommendations for clinical trials and daily practice. Ann Rheum Dis 2010;69(11):1913–9.

[5] Miloslavsky EM, Naden RP, Bijlsma JW, Brogan PA, Brown ES, Brunetta P, et al. Development of a Glucocorticoid Toxicity Index (GTI) using multicriteria decision analysis. Ann Rheum Dis 2017;76(3):543–6.

[6] Tugwell P, Boers M, Brooks P, Simon L, Strand V, Idzerda L. OMERACT: an international initiative to improve outcome measurement in rheumatology. Trials 2007;8(1):38.

[7] Beaton D., Maxwell L., Grosskleg S., Shea B., Tugwell B. The OMERACT Handbook Version 2.1 2021. Available from: https://omeract.org/handbook/.

[8] Maxwell LJ, Beaton DE, Shea BJ, Wells GA, Boers M, Grosskleg S, et al. Core domain set selection according to OMERACT filter 2.1: the OMERACT methodology. J Rheumatol 2019;46(8):1014–20.

[9] Black RJ, Robson JC, Goodman SM, Hoon E, Lai LYH, Simon LS, et al. A Patient-reported Outcome Measure for Effect of Glucocorticoid Therapy in Adults with Inflammatory Diseases Is Needed: report from the OMERACT 2016 Special Interest Group. J Rheumatol 2017;44(11):1754–8.

[10] Cheah JTL, Black RJ, Robson JC, Navarro-Millán IY, Young SR, Richards P, et al. Toward a core domain set for glucocorticoid impact in inflammatory rheumatic diseases: the OMERACT 2018 glucocorticoid impact working group. J Rheumatol 2019;46(9):1179–82.

[11] Cheah JTL, Robson JC, Black RJ, Goodman SM, Lester S, Mackie SL, et al. The patient's perspective of the adverse effects of glucocorticoid use: a systematic review of quantitative and qualitative studies. From an OMERACT working group. Semin Arthritis Rheum 2020;50(5):996–1005.

[12] Black RJ, Goodman SM, Ruediger C, Lester S, Mackie SL, Hill CL. A survey of glucocorticoid adverse effects and benefits in rheumatic diseases: the Patient Perspective. J Clin Rheumatol 2017;23(8):416–20.

[13] Hoon E, Ruediger C, Gill TK, Black RJ, Hill CL. A qualitative study of patient perspectives related to glucocorticoid therapy in polymyalgia rheumatica and giant cell arteritis. Open Access Rheumatol 2019;11:189–98.

[14] Robson JC, Dawson J, Cronholm PF, Ashdown S, Easley E, Kellom KS, et al. Patient perceptions of glucocorticoids in anti-neutrophil cytoplasmic antibody-associated vasculitis. Rheumatol Int 2018;38(4):675–82.

[15] Mirza SZ, Cheah JTL, Ghosh N, Robson JC, Hill CL, Singh J, et al. The patients' perspective of important glucocorticoid effects: a nominal group study among patients with systemic Lupus Erythematosus and Myositis. J Clin Rheumatol 2021;27(6):232–8.

[16] Tieu J, Cheah JT, Black RJ, Christensen R, Ghosh N, Richards P, et al. Improving benefit-harm assessment of glucocorticoid therapy incorporating the patient perspective: the OMERACT glucocorticoid core domain set. Semin Arthritis Rheum 2021;51(5):1139–45.

[17] Bridgewater S, Shepherd MA, Dawson J, Richards P, Silverthorne C, Ndosi M, et al. Measuring the impact of steroid therapy on health-related quality of life in patients with rheumatic diseases: international development of a glucocorticoid treatment-specific patient-reported outcome measure. Rheumatology (Oxford) 2023.

[18] Maxwell LJ, Beaton DE, Boers M, D'Agostino MA, Conaghan PG, Grosskleg S, et al. The evolution of instrument selection for inclusion in core outcome sets at OMERACT: filter 2.2. Semin Arthritis Rheum 2021;51(6):1320–30.

[19] D'Agostino MA, Beaton DE, Maxwell LJ, Cembalo SM, Hoens AM, Hofstetter C, et al. Improving domain definition and outcome instrument selection: lessons learned for OMERACT from imaging. Semin Arthritis Rheum 2021;51(5):1125–33.

[20] Boers M, Beaton DE, Shea BJ. OMERACT Filter 2.1: elaboration of the conceptual framework for outcome measurement in health intervention studies. J Rheumatol 2019;46(8):1021–7.

[21] Dixon WG, Suissa S, Hudson M. The association between systemic glucocorticoid therapy and the risk of infection in patients with rheumatoid arthritis: systematic review and meta-analyses. Arthritis Res. Ther. 2011;13(4):R139.

[22] Youssef J, Novosad SA, Winthrop KL. Infection risk and safety of corticosteroid use. Rheum. Dis. Clin. North Am. 2016;42(1):157–76.

[23] Lukert BP, Raisz LG. Glucocorticoid-induced osteoporosis: pathogenesis and management. Ann. Intern. Med. 1990;112(5):352–64.

[24] Nishimura J, Ikuyama S. Glucocorticoid-induced osteoporosis: pathogenesis and management. J Bone Miner Metab 2000;18(6):350–2.

[25] Mebrahtu TF, Morgan AW, West RM, Stewart PM, Pujades-Rodriguez M. Oral glucocorticoids and incidence of hypertension in people with chronic inflammatory diseases: a population-based cohort study. CMAJ 2020;192(12):E295–e301.

[26] Costello RE, Yimer BB, Roads P, Jani M, Dixon WG. Glucocorticoid use is associated with an increased risk of hypertension. Rheumatology 2020;60(1):132–9.

[27] Clore J.N., Thurby-Hay L. Glucocorticoid-induced hyperglycemia. Endocrine practice: official journal of the American College of Endocrinology and the American Association of Clinical Endocrinologists. 2009;15(5):469–74.

[28] Kwon S, Hermayer KL, Hermayer K. Glucocorticoid-induced hyperglycemia. Am. J. Med. Sci. 2013;345(4):274–7.

[29] Venter G, Tieu J, Black R, Lester S, Leonardo N, Whittle SL, et al. Perspectives of glucocorticoid use in patients with rheumatoid arthritis. ACR open rheumatology 2021;3(4):231–8.

[30] Wung PK, Anderson T, Fontaine KR, Hoffman GS, Specks U, Merkel PA, et al. Effects of glucocorticoids on weight change during the treatment of Wegener's granulomatosis. Arthritis Rheum 2008;59(5):746–53.

[31] Fardet L, Nazareth I, Petersen I. Long-term systemic glucocorticoid therapy and weight gain: a population-based cohort study. Rheumatology 2020;60(3):1502–11.

[32] Warrington TP, Bostwick JM. Psychiatric adverse effects of corticosteroids. Mayo Clin. Proc. 2006;81(10):1361–7.

[33] Brown ES, Khan DA, Nejtek VA. The psychiatric side effects of corticosteroids. Ann Allergy, Asthma Immunol 1999;83(6):495–503. Pt 1quiz -4.
[34] del Rincón I, Battafarano DF, Restrepo JF, Erikson JM, Escalante A. Glucocorticoid dose thresholds associated with all-cause and cardiovascular mortality in rheumatoid arthritis. Arthritis Rheumatol (Hoboken, NJ) 2014;66(2):264–72.
[35] Einarsdottir MJ, Ekman P, Molin M, Trimpou P, Olsson DS, Johannsson G, et al. High mortality rate in oral glucocorticoid users: a population-based matched cohort study. Front Endocrinol (Lausanne) 2022;13:918356.
[36] Nielsen SM, Uggen Rasmussen M, Boers M, AvdW D, de Wit M, T GW, et al. Towards consensus in defining and handling contextual factors within rheumatology trials: an initial qualitative study from an OMERACT working group. Ann Rheum Dis 2021;80(2):242–9.
[37] Uysal-Bozkir Ö, Parlevliet JL, de Rooij SE. Insufficient cross-cultural adaptations and psychometric properties for many translated health assessment scales: a systematic review. J Clin Epidemiol 2013;66(6):608–18.
[38] Fischer R, Ferreira MC, Assmar E, Redford P, Harb C, Glazer S, et al. Individualism-collectivism as Descriptive Norms:development of a subjective norm approach to culture measurement. J Cross Cult Psychol 2009;40(2):187–213.
[39] Romenti S, Murtarelli G, Miglietta A, Gregory A. Investigating the role of contextual factors in effectively executing communication evaluation and measurement. J Commun Manag 2019;23(3):228–45.
[40] Ciarrochi J, Sahdra B, Hayes S, Hofmann S, Sanford B, Stanton C, et al. A personalised-approach to identifying important determinants of well-being. OSF Preprints; 2023.
[41] Reber U. Overcoming language barriers: assessing the potential of machine translation and topic modeling for the comparative analysis of multilingual text corpora. Commun Methods Meas 2019;13(2):102–25.