



Measuring the impact of glucocorticoids from the patient perspective

- **Steroid PRO is a patient reported outcome measure to capture the impact of steroids from the patient perspective**
- **Validated for clinical trials and practice in inflammatory conditions**
- **15 items: 4 domains and a total score.**
- **Developed following FDA guidance for the development of PROs**

Psychological impact

- Restless or physically agitated
- Anxious, panicky, fearful
- Difficulty thinking clearly
- Talked too much, too fast or too loudly
- Irritable or angry with others

Impact on appearance

- Unhappy with appearance (change in face or body shape)
- Worried about weight
- Difficulty with clothes not fitting

Treatment concerns

- Upset or annoyed about having to take steroids
- Upset or annoyed about taking extra medications to prevent side effects
- Worried about the long-term risks of treatment

Social impact

- Avoided being with other people
- Problems with fatigue or tiredness
- Problems joining in with others
- Difficulty with everyday responsibilities

You got all types of problems behind it that you never had before. That's the main thing, and they're serious problems. I mean serious problems. The weight gain, pre-diabetic (Male patient, Lupus)¹

'It's obvious you guys know what you're talking about—these are my issues. It's very validating when you realise it's not just you. These problems are real and they matter.... These are not questions my doctor asks me about (Female patient, Asthma)³.

1. Underpinning in-depth qualitative interviews

- 60 patients with rheumatic diseases treated with glucocorticoids from UK, USA and Australia
- Bridgewater ***Rheumatology*** 2023

<https://innovation.ox.ac.uk/licence-details/steroid-patient-reported-outcome-measure-steroid-pro>

Validated (Rasch/Factor analysis/construct/test-retest/ known groups) in >900 patients from UK, USA and Australia

- Giant cell arteritis and polymyalgia rheumatica
 - Inflammatory arthritis (rheumatoid arthritis, psoriatic arthritis, enteropathic arthritis, reactive arthritis).
 - Systemic vasculitis (ANCA associated vasculitis, Behcets, polyarteritis nodosum, IgG4 disease)
 - Connective tissue disease (Lupus, Sjogrens disease, myositis)
- Bridgewater ***Ann Rheum Dis*** 2024

3. Validated (cognitive interviews) 42 patients and 14 clinicians from the UK and USA

- Inflammatory lung disease (Asthma, Chronic obstructive lung disease, Interstitial lung disease, Sarcoidosis)
 - Inflammatory skin disease (Eczema, Bullous pemphigoid, pemphigus, cutaneous lupus and dermatomyositis)
 - Inflammatory bowel and liver disease (Ulcerative colitis, Crohn's disease, autoimmune liver disease)
- Sweeney ***BMJ Open*** 2024