

M. Barnett, J. McNamara, W. Wilson, J.L. Pipicella, S. Ghaly, R. Gearry, J. Begun, A.J. Williams, K. Lynch, I. Lawrance, M. Schultz, G. Walker, G. Radford-Smith, S.J. Connor, J.M. Andrews

*The individual authors have no personal potential conflicts of interest to disclose with regards to this work*

## BACKGROUND

- Ustekinumab is a human monoclonal antibody targeting interleukin-12 & 23 with established efficacy in Inflammatory Bowel Disease (IBD).
- Some people on standard dosing of ustekinumab have persistent disease activity, necessitating dose escalation (DE).
- Aim: to investigate the frequency and outcomes of escalated dosing regimens in a large Australasian cohort.

## METHODS

- Crohn's Colitis Care is a cloud-based IBD-specific electronic medical record (EMR) used at IBD centres across Australasia since 2018.
- Data from CCCare flow across to a de-identified clinical quality registry, which was interrogated in November 2023.
- DE was defined as maintenance dosing >90mg subcutaneously Q8 weekly and/or additional induction doses.

## RESULTS

- Of the 790 people receiving ustekinumab, 43.4% were on DE therapy.
- 86.1% had Crohn's Disease, 11.3% had Ulcerative Colitis, and 1.6% were IBD-unclassified.
- Median age: 40 years (IQR 30-52)
- Even gender distribution (50.3% female).
- Median age at diagnosis: 25 years (IQR 18-38)
- Median time to DE: 6 months (IQR 1-15).
- 84.5% of those on DE ustekinumab continued on therapy beyond 12 months.

## CONCLUSIONS

These prospectively collected data from large Australasian IBD treatment centres show:

- Close to half of those receiving Ustekinumab required DE.
- DE led to reduced systemic steroid use and improved endoscopic, PRO2 and faecal calprotectin remission rates at 12 months.
- These data can be used to perform health economy analysis to determine the price points at which DE is cost effective.

## RESULTS (CONT.)

- Rates of faecal calprotectin remission (<250ug/g), endoscopic remission and patient reported outcome (PRO2) remission were higher 12 months post DE.
- Systemic steroid requirements fell significantly 12 months post DE.
- The number of endoscopies and radiological investigations fell at 12 months post DE, while the rates of hospital admissions did not significantly differ between the DE and standard cohorts.
- The number of clinical assessments per person fell from 1.2 pre-DE to 0.9 post DE.

Outcome measure	Pre-DE	12 months post-DE	P value
Faecal Calprotectin Remission (<250ug/g) (%)	47.9	60.0	.034
Patient-Reported Outcome Remission (%)	75.5	85.0	.006
Radiological Remission (%)	77.7	72.3	.370
Endoscopy Remission (%)	22.6	46.3	.001
Systemic Steroid Use (%)	9.0	2.6	.001
Hospital Admissions (n)	43	31	.153
Endoscopies (n)	194	126	.001
Radiology (n)	266	170	.001

