patients; the thresholds of benefit that would produce adherence were also assessed.

Methods Four methods of displaying information about the benefits of maintenance therapy in remission were explained to UC patients in remission, during face to face structured interviews. These were largely conventional numerical approaches: relative risk reduction [RR], absolute risk reduction [AR], number needed to treat [NNT]. The fourth was an optical representation via Cates plot [CP]). Patients understanding and preference for each approach were recorded. Patients were asked to state the minimum thresholds required to adhere to a hypothetical medication (with 5-ASA like properties) for the benefits of relapse and cancer reduction respectively. Thresholds were determined for each method of display.

Results Of 50 participants (mean age 50 years; 58% male) 48% preferred data presentation by RR over CP (28%), AR (20%) and NNT (4%). 94% found RR easy to understand, better than CP (74%), AR (88%) or NNT (48%). Thresholds required for adherence also differed between methods. For bowel cancer prevention, 94% indicated adherence for benefit levels of 61% RR or lower but only 57% would adhere when presented with the corresponding CP ($p<0.001$). For relapse prevention, 78% of patients chose a threshold of 40% or lower but only 43% chose the corresponding CP ($p<0.001$). When presented with RR, adherence minimum thresholds equivalent or lower to the actual 5-ASA benefits were applied by 98% of patients for cancer reduction and 78% for flare reduction.

Conclusion Ulcerative colitis patients prefer RR and CP as methods to display medication benefit. NNT is poorly understood and unpopular. Patients apply significantly higher thresholds for adherence when presented with CP in comparison to RR. Presented with information in this way, most patients would choose to adhere to 5-ASA medication when offered the actual benefit profile. Reduction of cancer risk may be a stronger motivator than maintenance of remission. Interventions to improve 5-ASA adherence should use RR and convey benefits for cancer and flare prevention.

Competing interests C Selinger: Grant/Research Support from: Shire, Ferring, Nycomed, Y Kinjo: None declared, J McLaughlin: None declared, A Robinson: None declared, R Leong: Grant/Research Support from: Shire, Ferring, Nycomed.

PMO-242 THE IBD-CONTROL QUESTIONNAIRE: DEVELOPMENT AND PSYCHOMETRIC VALIDATION OF A TOOL FOR CAPTURING DISEASE CONTROL FROM THE PATIENT PERSPECTIVE FOR USE IN ROUTINE CARE

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Introduction Although a range of disease activity measures and QoL questionnaires is available for IBD, none has found a place in routine clinical practice. This project aimed to develop a tool for capturing disease control from the patient's perspective with measurement properties appropriate for routine clinical practice.

Methods Phase I: Systematic review of existing PROMS, patient focus groups and a steering group to define domains and items for the "**IBD-Control**". Instrument comprises 13 questions items plus a visual analogue scale (VAS, 0–100) for overall control. **Phase II**: Prospective validation, patient completion of IBD-Control, QoL questionnaire (UK-IBD-Q), EuroQol (EQ5D), Hospital Anxiety & Depression Score (HADS); clinician assessment (blinded to questionnaire) recording disease activity (Harvey Bradshaw Index, HBI; or Simple Clinical Colitis Activity Index, SCCAI), global clinician assessment (remission; mild; moderate; severe), Montreal Classification, treatment history. Ongoing longitudinal survey (serial questionnaires).

Results 194/200 returned baseline surveys (CD, n=107; UC, n=87). **Study population** (CD, UC): Age (mean): 41; 48 yrs. Disease duration (mean): 10.5; 10.7 yrs. Prev. Surgery (%): 50%; 3.4%. Immunosuppressants (%): 49.5%; 27.6%. Biologics (%): 22.4%; 8.0%. Disease activity (mean [SD] HBI; SCCAI): 5 [5]; 4 [3]. **Measurement properties of IBD-Control:** Completion time (mean [SD]): 1 min 15 s [25s]; Internal consistency: Cronbach's α for all 13 items: 0.838; for sub-group of 8 questions (IBD-Control-8): 0.841. Strong correlation between IBD-Control-8 sub-score and IBD-Control-VAS (r=0.79). Test-retest reliability for stable patients (Baseline vs 2 week repeat, no change): IBD-Control-8, 15.8 vs 15.6; p=0.73; IBD-Control-VAS, 65.5 vs 68.0, p=0.33. Validity: Moderate-to-strong correlations between IBD-Control-8 subscore and IBD-Control-VAS vs disease activity, UK-IBD-Q and global health state (utility) with r values 0.56 to 0.84. Discriminant validity (mean scores for remission, mild, moderate, severe): ANOVA $p<0.01$. Sensitivity to change: (analysis of first 53 follow-ups): No significant changes for stable patients; moderate-to-large responsiveness statistics for IBD-Control-8 and IBD-Control-VAS: (Effect sizes: 0.4–1.6).

Conclusion The IBD-Control shows promise as a rapid (<2 min), reliable, valid and sensitive instrument for measuring overall disease control from the patients perspective. Unlike existing PROMS, its ease-of-use and generic applicability make it a candidate for use in routine practice as a decision-support tool for patients and clinicians.

Competing interests C Ormerod: None declared, D Shackcloth: Grant/Research Support from: Abbott Laboratories Ltd, M Harrison: None declared, E Brown: None declared, K Bodger: Grant/Research Support from: Abbott Laboratories Ltd.

PMO-243 FAECAL CALPROTECTIN ANALYSIS: DOES THE METHOD MATTER?

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Introduction Faecal calprotectin (FC) is a sensitive marker of intestinal inflammation and is useful to help distinguish between organic and non-organic (functional) disease. The increasing popularity of this test, with various analytical methods available, potentially leads to confusion in interpreting results. The aim of this study was to technically evaluate FC measured by different ELISA methods in secondary/tertiary care.

Methods 62 stool samples were collected from sequential outpatients presenting with chronic diarrhoea. All participants had a colonoscopy with biopsy, to which FC results were compared. FC was measured by ELISA assays: Immundiagnostik PhiCal (version 1) and Buhlmann EK-CAL. A subset were also measured by PhiCal (version 2). Stool was weighed and extracted, and ELISAs performed manually.

Results 38 patients with IBD/other organic bowel disease (mean 36 yrs, range 15–49) and 24 patients with IBS (mean 36 yrs, range 20–48) were sampled. Sensitivity and specificity for active IBD vs IBS using manufacturers' cut-offs of 50 μg/g were: Buhlmann EK-CAL 86% (95% CI 42 to 99) and 60% (95% CI 33% to 83%), PPV 50% (95% CI 22% to 78%), NPV 90% (95% CI 54% to 99%); PhiCal1 78% (95% CI 40% to 96%) and 92% (95% CI 60% to 100%), PPV 88% (95% CI 47% to 99%) and NPV 86% (95% CI 56% to 97%). Correlation across full range of results were PhiCal1 vs EK-CAL, $R^2=0.45$; PhiCal2 vs PhiCal1, $R^2=0.54$. However for results <100 μg/g by PhiCal1, correlations improved that is, $R^2=0.64$ and $R^2=0.83$ respectively. Intra-batch imprecision of the whole process,

including extraction of native stool, was assessed at a range of clinically relevant concentrations: Buhlmann EK-CAL 17% (10 μg/g), 12% (47 μg/g), 19% (62 μg/g); PhiCal1 21% (8 μg/g), 24% (10 μg/g), 18% (27 μg/g); PhiCal2 19.5% (18.9 μg/g). Inter-batch imprecision of ELISA analysis was lower: Buhlmann EK-CAL 8.6% (30 μg/g), 5.8% (129 μg/g); PhiCal1 6.2% (39 μg/g), 10.8% (135 μg/g); PhiCal2 8.9% (33 μg/g). Functional sensitivity: Buhlmann EK-CAL 10 μg/g; both PhiCal 20 μg/g. Assays were found to be linear (without further sample dilution) up to 600 μg/g for EK-CAL, PhiCal1 400 μg/g, PhiCal2 800 μg/g. Mean recovery in spiked stool samples: Buhlmann EK-CAL 98%, PhiCal1 83%, PhiCal2 79%.

Conclusion All three ELISA assays evaluated have relatively high coefficients of variation compared to other laboratory tests, due to heterogeneity of stool material and manual extraction/analysis. Results from different FC methods are not directly comparable, despite widespread adoption of single cut-offs. Using 50 μg/g cut-off, PhiCal1 performed better than Buhlmann EK-CAL in distinguishing IBD from IBS in our study. There is improved assay linearity using PhiCal2. Clinicians should be aware of type of ELISA methods employed when interpreting FC results, and cut-offs used should be fully evaluated.

Competing interests None declared.

PMO-244 INFLIXIMAB REDUCES THE NEED FOR CORRECTION OF FISTULAE AND DRAINAGE OF ABSCESSES: A UK RETROSPECTIVE STUDY OF CROHN'S DISEASE PATIENTS

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Introduction Crohn's disease affects 50–100 patients per 100 000 in the population and typically follows a progressive course, with fistulae occurring in 17% to 43% of patients. The most common type of fistulae, perianal, have been shown to decrease quality of life and increase the likelihood of total colectomy. This retrospective study assessed incidence of procedures to correct fistulae and drain abscesses for a UK cohort of patients being treated with infliximab.

Methods 18 UK centres participated in the study, including data from a total of 380 individuals with Crohn's disease who had received their first infusion of infliximab after 1 January 2003. Patients were eligible for inclusion with 12 months data prior to, and 24 months data post infliximab initiation, in their clinical record. Data on all investigations, clinic appointments, admissions and operations were extracted from the patient record in a standardised manner by members of the local clinical team. A prespecified statistical analysis plan compared healthcare resource utilisation at 12, 18 and 24 months after the introduction of infliximab with resource utilisation during the 12 months prior to starting treatment.

Results In the 12 month period before initiation of infliximab therapy there were a total of 32 procedures within the study population to correct fistulae, treat severe anal fistulae or drain abdominal or peri-rectal abscesses. In the 24-month period following initiation of infliximab therapy there were significantly fewer cumulative procedures (13 total). Procedures undertaken for correction of fistulae reduced from 12 (3.2% of patients) in 12 months pre-infliximab to 7 (1.9% of patients) in the 24 months following infliximab initiation ($p<0.05$). Treatment of severe anal fistulae was reduced from six cases (1.6%) to 2 (0.5%) ($p<0.01$). Procedures undertaken to drain either abdominal or peri-rectal abscesses reduced from 14 (3.7%) to 4 (1.1%) over the same period ($p<0.0001$).

Conclusion In a large UK cohort of Crohn's disease patients, treatment with infliximab was shown to significantly reduce the need for surgical procedures relating to either fistulae correction or drainage of abscesses

Competing interests C Wheeler: Employee of: MSD, R Chipperfield Employee of: MSD, T Orchard: Grant/Research Support from: MSD, Warner Chilcott, Johnson and Johnson, Consultant for: Warner Chilcott, Ferring, Shire, Speaker bureau with: Warner Chilcott, Ferring, Shire, J Lindsay: Grant/Research Support from: MSD, Abbott, Shire, Consultant for: MSD, Abbott, Shire, GSK, Ferring, Warner Chilcott, Atlantic Healthcare, Speaker bureau with: MSD, Abbott, Shire, Ferring, Warner Chilcott.

PMO-245 INFLIXIMAB REDUCES RATES OF EMERGENCY HOSPITAL ADMISSIONS AND SURGICAL PROCEDURES: A UK RETROSPECTIVE STUDY OF CROHN'S DISEASE PATIENTS

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Introduction Crohn's disease affects 50–100 patients per 100 000 in the population and typically follows a progressive course, with an estimated 33% of patients with active disease developing complications requiring hospitalisation or surgery in the first year of diagnosis. Up to 80% of patients require surgery at some point during the course of their disease. This retrospective study assessed the rates of emergency hospitalisation and surgery for a large UK cohort of patients before and after infliximab therapy.

Methods 18 UK centres participated in the study, including data from a total of 380 individuals with Crohn's disease who had received their first infusion of infliximab after 1 January 2003. Patients were eligible for inclusion with 12 months data prior to, and 24 months data post infliximab initiation, in their clinical record. Data on all investigations, clinic appointments, admissions and operations were extracted from the patient record in a standardised manner by members of the local clinical team. A prespecified statistical analysis plan compared healthcare resource utilisation at 12, 18 and 24 months after the introduction of infliximab with resource utilisation during the 12 months prior to starting treatment.

Results In the 12-month period before initiation of infliximab therapy there were a total of 12 emergency admissions for surgical procedures. There were 176 unplanned emergency admissions in the same period to manage complications such as bowel obstruction or flare. In the 24-month period following initiation of infliximab therapy there were significantly fewer cumulative emergency admissions for surgical procedures (8 total, $p=0.0184$) and management of complications (220 total, $p<0.0001$). The most common complications resulting in unplanned admissions included abscess, flare and intestinal obstruction which were reduced by half in the first year of infliximab therapy.

Conclusion In a large UK cohort of Crohn's disease patients, treatment with infliximab was shown to significantly reduce rates of emergency admissions for either surgical intervention or management of complications.

Competing interests C Wheeler: Employee of: MSD, R Chipperfield: Employee of: MSD, T Orchard: Grant/Research Support from: MSD, Warner Chilcott, Johnson and Johnson, Consultant for: Warner Chilcott, Ferring, Shire, Speaker bureau with: Warner Chilcott, Ferring, Shire, J Lindsay Grant/Research Support from: MSD, Abbott, Shire, Consultant for: MSD, Abbott, Shire, GSK, Ferring, Warner Chilcott, Atlantic Healthcare, Speaker bureau with: MSD, Abbott, Shire, Ferring, Warner Chilcott.