OTU-26 DATA DRIVEN SERVICE EVALUATION OF AN IBD HELPLINE

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Introduction We present a data driven service evaluation of the use of an Inflammatory Bowel Disease (IBD) telephone helpline service at a single UK IBD centre (UHS). We demonstrate how such evaluation can highlight service improvement needs to maximise efficiency and improve patient care.

Methods IBD patients at UHS can call our helpline and leave a message for one of our IBD specialist nurses to respond to the following working day. All helpline activity is electronically logged in the electronic health record. Anonymised data was systematically extracted for the first 6 months of 2016, 2017 and 2018. Calls were categorised as follows: 1) flare call – symptoms relating to IBD, 2) follow up call – following change in medication/results, 3) medication enquiries, 4) administrative calls and 5) unsuccessful unanswered calls.

Results A total of 7,046 calls were analysed. Activity increased through the study period with 1627, 2676 and 2743 attempted/successful outgoing calls made to 598, 785 and 882 unique patients in the first six months of 2016, 2017, 2018 respectively (table 1).

Abstract OTU-26 Table 1 Breakdown of call numbers and time taken for first 6 months of each year

	Number of calls (Time in hours)		
	2016	2017	2018
Flare	602 (210.5)	912 (324.2)	967 (352.1)
Follow-up	282 (90.6)	457 (123.1)	450 (124.8)
Medication	223 (52.4)	305 (79.9)	385 (112.3)
Administration	104 (19.4)	181 (38.3)	172 (42.8)
Unsuccessful	416 (19.7)	821 (53.1)	769 (56.1)
Total	1627 (392.6)	2676 (618.6)	2743 (688.1)

In total 28.5% of calls were unsuccessful. The 416, 821 and 769 unsuccessful calls were made to 228, 388 and 384 unique patients respectively with associated preparation time of 19.7, 53.1 and 56.1 hours (hrs). Call success was similar for each weekday but showed a trend to improvement towards the end of each day (after 4pm).

Administrative calls for 2016, 2017 and 2018 included patients requesting test results which generated 52 (10.5 hrs), 87 (20.0 hrs) and 105 (26.5 hrs) calls and appointment queries which generated 23 (4.1 hrs), 41 (7.9 hrs) and 21 (5.4 hrs) calls respectively.

Conclusions Use of our IBD helpline has increased over time. When using incoming call requests as a marker of activity it is important to recognise that approximately half of these require follow-up calls to review results and treatment plans. This must be considered when designing services. Time wasted in unsuccessful calls is substantial and novel methods to reduce this are needed. Online access to results and appointments may reduce total calls. An online portal (My Medical Record) for medication information, results and admin queries

as well as a pre-call text message are being introduced at UHS.

OWE-01 THE EFFECT OF INFLIXIMAB DOSE ESCALATION IN INFLAMMATORY BOWEL DISEASE PATIENTS WITH ANTIBODIES TO INFLIXIMAB

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Introduction Infliximab (IFX) dose escalation (DE) can be used in patients with inflammatory bowel disease with loss of response (LOR) or subtherapeutic drug levels. However, the long-term benefit of DE remains unclear, especially in those with antibodies to infliximab (ATI).

Aim To assess the effect of DE in patients with ATI on drug level, clinical response and ATI status.

Methods IFX and ATI trough levels (Immundiagnostik, UK) were measured at each IFX infusion in patients from May 2016 at a large referral centre and results retrospectively reviewed in December 2018. DE comprised a reduction in dose interval between maintenance infusions <8 weeks ± an increase dose of IFX to 10 mg/kg. Clinical remission was defined for Crohn's disease (CD) as Harvey Bradshaw Index ≤4 + C-reactive protein ≤5 mg/L and for ulcerative colitis as Simple Clinical Activity Index ≤4. ATI >10 mg/L is considered 'positive' by manufacturer. Positive ATI that resolved within two consecutive infusions were defined as transient.

Results 78 patients were dose escalated (41 male; 40 CD; age 17–81; 51 on immunosuppression): 48 for LOR and 30 to optimise therapeutic drug monitoring levels. 73 received DE for a median 36 weeks (range 4–140). 5 patients stopped IFX after 1 further dose: 2 for LOR and 3 for infusion reaction (IR). At the time of DE, 31/78 (40%) patients had ATI >10 mg/L (ATI+). In patients with ATI ≤/≥10 mg/L, DE significantly increased drug levels: median IFX levels of 1.3 and 0.9 respectively at baseline to 3.1 and 3.5 at week 24 (figure 1). After DE, 13/33 ATI+ had a fall in ATI ≤10 mg/L: median pre-DE ATI 23 mg/L (range 10–86), median post-DE ATI 9

Abstract OWE-01 Figure 1 Median IFX levels following dose escalation
IFX levels at follow up compared to baseline *p<0.01 **p=0.06

mg/L. Pre-DE ATI levels in those without a fall in ATI ≤ 10 mg/L did not differ significantly from those where a fall was seen: median 65 mg/L (range 10–455). Acute IR following DE occurred in 3 patients with ATI >10 mg/L vs 0 in the transient/ATI- group ($p=0.06$). At week 24 following DE, 16/31 ATI+ patients were in clinical remission (10 recaptured after LOR; 6 maintained clinical remission) vs 30/47 ATI- patients (22 recaptured after LOR; 8 maintained clinical remission). Duration of clinical remission was shorter in ATI+ patients (median 24 weeks, range 0–88) than in those with transient/ATI- (median 36 weeks, range 0–126, $p=0.06$).

Conclusions A strategy of DE for selected patients receiving IFX is associated with an increase in drug levels and a reduced rate of ATI positivity. This is associated with clinical remission in approximately 50% of patients at 6 months but the duration of this response is shorter in those with ATI >10 mg/L compared to those undergoing DE without ATI >10 mg/L.

OWE-02 THE IBD BIORESOURCE: PROGRESSING FROM GENETICS TO FUNCTION AND CLINICAL TRANSLATION IN CD & UC

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Introduction He Inflammatory Bowel Disease (IBD) BioResource was established by the UK IBD Genetics Consortium and the NIHR BioResource in 2016 to expedite functional characterisation of IBD-associated variants and clinical translation of recent genetics advances. It aims to recruit 25,000 patients, across hospitals sites nationwide, who can then be further invited for future research studies based on genotype and/or phenotype.

Methods The Main cohort comprises individuals with established Crohn's Disease (CD) and Ulcerative Colitis (UC). Both clinical and self-reported phenotype data are collected, alongside plasma, serum and DNA samples for Whole Genome Sequencing. The Inception cohort aims to recruit a sub-set of 1,000 individuals newly diagnosed with IBD that will provide more detailed sampling, unconfounded by drug treatment or effects of surgery and includes stool, biopsy tissue and whole blood for RNA. This cohort offers a unique resource to undertake omics studies and facilitate research into determinants, predictors and biomarkers of IBD disease course and treatment response. The IBD BioResource panel can be accessed by any investigators with ethically approved proposals and may involve a range of possible options, such as access to data/samples or recall of genotype-selected participants to donate further samples or trial novel therapies.

Results

Main cohort Recruitment is still going strong and we now have over 20,000 patients enrolled into our IBD BioResource panel.

Inception cohort This has now been up and running fully since March 2018. We have >40 hospital sites trained to identify and recruit to this cohort. Recruitment is going well too, with 10% of our target reached so far.

Translation One measure of success for IBD BioResource is the use of its panel for the facilitation of IBD research. To

date 12 'Stage 2 studies' have applied to utilise the IBD BioResource. Of the 12 applications, $\sim 40\%$ requested access to anonymised samples and data while the remaining $\sim 60\%$ required involvement of participants (recall to sites/completion of online questionnaires). Field of studies ranged from disease mechanistic, immunology through to genetic, environmental and microbial interactions.

We aim to give further update about the current state of the project, which will be over 3 years. This will include key achievements and milestones reached, the 'highs and lows' of setting up large cohort of patients and highlights on selected stage 2 studies.

Conclusion The IBD BioResource and its network are on course to fulfil their goals.

OWE-03 HIGHER SERUM GOLIMUMAB CONCENTRATIONS ARE ASSOCIATED WITH COMBINED CLINICAL-BIOCHEMICAL REMISSION: RESULTS FROM THE GO-LEVEL STUDY

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Introduction The exposure-response relationship associated with the use of golimumab for UC has been previously demonstrated in the PURSUIT trial program. A significant association between serum golimumab concentrations (SGC) and favourable outcomes was observed during both induction and maintenance therapy. However, data regarding the optimal therapeutic SGC threshold is limited.

Methods GO-LEVEL was an open-label, phase IV study (NCT03124121) which included a prospective cohort commencing induction therapy as well as a cross-sectional cohort of patients receiving maintenance treatment (defined as a minimum of 18 weeks from initiation). Here we report the results of the maintenance study.

Patients receiving maintenance therapy were recruited either at the point of flare, or during stable remission. Clinical disease activity was evaluated using SCCAI and PRO2, biochemical activity using faecal calprotectin (FC) and CRP and QoL using the IBD-Control questionnaire. Clinical remission was defined as SCCAI <3 .

Combined clinical-biochemical remission was defined as SCCAI <3 as well as FC <250 ug/g. SGC and anti-golimumab antibodies (AGA) were measured using a drug-sensitive ELISA (LISATRACKER, Theradiag). Samples were collected within 7 days of the subsequent administration.

Fishers Exact or Mann-Whitney U were used to compare groups and ROC analysis to identify therapeutic threshold.

Results In total, 49 patients on maintenance treatment were recruited; 31 in clinical remission and 18 at the point of flare. There was no significant difference in median SGC between the two groups (2.7 vs 2.1ug/ml, respectively, $p=0.27$).

Of the 46 patients with FC data available, 24 were in combined remission, 22 were not. The median SGC of those in combined remission was significantly higher than those who were not (3.0 vs 2.0ug/ml, respectively, $p=0.031$). Univariate analysis comparing groups can be seen in table 1. ROC curve analysis demonstrates 2.1ug/ml as the optimal therapeutic