IBD Registry

IBD Biological Therapies Audit

Annual Report 2023

September 2023

IBD Biological Therapies Audit – Annual report 2023

1 Foreword

The IBD Registry is pleased to publish our 2023 annual report on the use of biological therapies in the treatment of inflammatory bowel disease (IBD).

This year has been an exceptionally busy year in terms of delivering on the increasing elements of Quality Improvement (QI) for IBD in the UK. These have all been undertaken to drive improvements in clinical outcomes and patient experience, and we are proud to have been working at the heart of all of these.

The first of these was the British Society of Gastroenterology (BSG)'s IBD Section initiative to fully revise the IBD clinical KPIs, which was completed in June of this year with formal publication in Frontline Gastroenterology[1] following a two-stage Delphi process with key stakeholders in the clinical and patient communities. The second has been the IBD UK Benchmarking Surveys, which we supported with data collection and management. These have had an excellent response, reaching over 15,000 patients and covering 147 IBD services. We hope that both these initiatives will contribute to improving and reducing the individual variation of IBD care across the UK.

The Registry is at the heart of delivering these important QI programme. The sustained participation of IBD teams in the biologics and other advanced therapies audit is key to understanding the care they provide and developing their service.

On behalf of the ultimate beneficiary, the person living with IBD, we are extremely grateful and offer thanks to all the IBD teams and our partners for their continued support.

Prof Stuart Bloom

Chief Medical Officer, IBD Registry

2 Summary

The national clinical audit of biological therapies is the long-running programme for quality improvement activity in the UK for people with IBD. This programme is a rolling assessment, based on clinical data captured as far as possible at the point of clinical care to provide a representative picture of the care and treatments that patients receive. In addition to managing the data collection activities, the IBD Registry also undertakes a number of analyses in order to provide actionable insights back to the IBD teams, as part of the data to information to change cycle. Participating teams receive a report of performance each quarter, with an annual overview (this report) published once per year.

To bring the national audit up to date, the IBD Section of the BSG have revised the biologic therapies audit and introduced new Key Performance Indicators (KPIs) that additionally assess the time from referral to first treatment and the use of corticosteroids. Whilst transition to these new metrics is underway, this report reviews the previous KPIs, examines the differences in performance of longstanding and newer participants in the audit, and reviews the availability of existing information held by the Registry on use of steroids and on data completeness. Finally, we introduce a new graphical method for reporting performance that participants may find more intuitive and helpful for action.

As the organisational complement to the clinical audit covered in this report, the IBD Registry has been working as part of IBD UK (a coalition of organisations working together in IBD) to define and deliver in 2023 a pair of benchmarking surveys on the organisational aspect of the care that they receive, based against the IBD Standards (*https://ibduk.org/ibd-standards*). The patient survey engaged with patients to seek their views on the care they are receiving while the service survey enabled the hospital IBD service teams to self-report their provision. The data collection for these IBD UK 2023 Benchmarking Surveys has been conducted by the IBD Registry, and the first reports are expected from IBD UK later in Autumn 2023.

3 Acknowledgements

This work is based on analysis of patient-level IBD data held by the IBD Registry. This would not be possible without the help and support of the participating IBD hospital teams, and we thank them for their key role in collecting this important resource, together with everyone with IBD (Crohn's disease, ulcerative colitis or another form of inflammatory bowel disease) who has given permission for their data to be held by the Registry.

We are grateful to our clinical leads: Prof Stuart Bloom, Dr Keith Bodger, Dr Fraser Cummings and Dr Nick Kennedy for their oversight of Registry reports, together with Liz Dobson and Dr Stephen Grainger for the operational and clinical management of the production of this report.

We would also like to acknowledge and thank the IBD Registry team involved in the analysis, presentation, and distribution of these reports: Dr Leena Sinha, Fred Taylor, Sarah Miles, Ami Saito, Cressida Ward and Megan Harrison.

4 Quality improvement in inflammatory bowel disease

There are now a number of elements to quality improvement in IBD in the UK. Led by the British Society of Gastroenterology, the existing biologics audit has been reviewed, revised and extended (see Section 6). Running in parallel with these changes to the national audit, in 2023 (as in 2019) IBD services have been invited to complete a self-assessment survey and people with IBD have been invited to complete a survey on the care they receive from their IBD practitioners. The platforms for collecting all these data have each been provided by the IBD Registry. The two surveys are overseen by IBD UK, who will publish the results later this year and consider how the current IBD Standards might be adjusted in the light of the findings.

During the transition to the new revised KPIs, submission of data by IBD clinical teams has continued. The IBD Registry have published individual quarterly reports to each team on the quality, completeness, and depth of the data they submit, with the aim of providing insights on their data and the opportunity to make changes that might assure the submission of more complete information on the cases they are treating.

In order to receive data for analysis of the new KPIs, the Registry dataset has been updated and a new online tool, focussed on easy collection of these KPIs, has been created. The tool is currently being piloted by a small number of IBD teams, with rollout planned for early 2024. The target users for this new tool are IBD teams who do not currently have an alternative data collection system – such as a bespoke IBD clinical system or as part of a hospital-wide electronic patient record.

Since 2022, to allow more agile updating of the data we receive and the creation of an identifiable registry, we have permissions to receive data direct to our Data Access Portal, rather than via NHS Digital. This change in dataflow is described in our updated consent materials and has also been approved by the Confidentiality Advisory Group.

5 National IBD clinical audit

To align with previous annual reports, we reproduce here the trends in clinical audit KPIs for the three years up to 2022 i.e. when the last data submissions via NHS Digital were received.

Table 1: performance trends in clinical audit KPIS 2019 - 2022

	Cumulative to Jan 2020	Cumulative to Jan 2021	Cumulative to Jan 2022	Trend
Cumulative total of adult patients eligible for audit	6,411	8,315	10,329	
KPI 1: Complete pre-treatment screening	71%	74%	76%	
KPI 2: Disease activity assessment at initiation (PGA included)	67%	64%	62%	
KPI 3: Registry consent (note: no longer part of audit)	45%	46%	43%	
KPI 4: Review at 3 months	41%	41%	41%	
KPI 5: Disease activity assessment recorded of those reviewed at 3 months (PGA included)	64%	62%	62%	
KPI 6: Review at 12 months	36%	35%	35%	
KPI 7: Disease activity assessment recorded of those reviewed at 12 months (PGA included)	67%	61%	60%	

We have commented before that there has been a steady improvement in pretreatment screening of patients (KPI-1) before the initiation of their first treatment with a biological therapy – an important aspect of the safe use of these powerful agents. Reporting of reviews at three and twelve months after the start of treatment (KPI-4, KPI-6) plateaued in the three years to 2022. These results, in the face of the impact of COVID-19, are a remarkable testament to the continuity of care IBD teams achieved.

Please note in the table above that KPI-3 (Registry consent) is no longer considered a performance indicator for clinical teams as we now receive consent directly from patients.

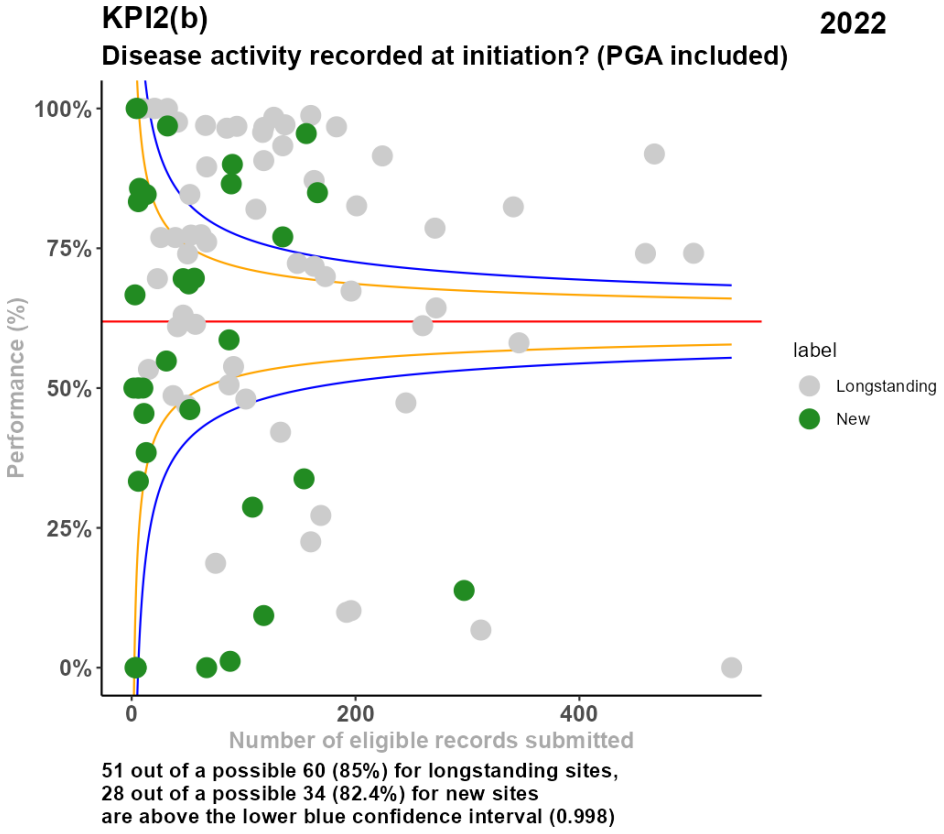
The data analysed for this report were received up to April 2022. Data submitted to our new submission platform (from July 2022 onwards) will be included in our Annual Report next year.

5.1 New and more established teams participating in the national audit

The data submitted for the audit are cumulative – that is, the new and updated records are received with all the data that a team has previously submitted. This has the advantage of ensuring ongoing continuity of data even if teams are unable to submit at every quarterly submission date, as well as simplifying the extraction of data from data capture systems. However, this cumulative method has the downside that more recent changes in performance may be masked by the 'weight' of earlier records, particularly if there was a bulk submission, or some other disproportionate level of data in the earlier days. To examine whether IBD teams who more recently began participating in the audit had performance that differed from longstanding participants, we have used the virtues of funnel plots to investigate this difference.

The figure below shows the performance of all participating adult teams for a sampled metric (here, KPI-2: disease assessment at the initiation of biologic treatment), divided into those who have participated for more or less than two years. As the audit has been hosted by the IBD Registry since 2016, this means that 'new teams' are defined as those who submitted data only since 2020, while 'longstanding teams' began submitting data any time from 2016-2019.

Figure 1: performance of all participating adult teams for KPI-2 (disease assessment at the initiation of biologic treatment)



Performance is reflected by the location of each data point in relation to the average (red line) and control limits (yellow and blue lines). The funnel shape of the control

limits takes account of the number of records assessed in calculating each data point. Outliers appear outside (below or above) the blue control limits (the 99.8% confidence interval).

The table below reports the percentage of longstanding and new teams whose performance is above the lower blue control limit for each KPI. This can be considered within range of the national average.

Table 2: Percentage of IBD teams (above the 99.8% lower confidence interval) grouped by duration of participation with the IBD Registry

KPI	Longstanding sites (n=60) %	New sites (n=34) %	Overall (n=94) %
KPI1	81.8	91.1	86.5
KPI2a	71.7	76.5	73.4
KPI2b	85	82.4	84
KPI3	71.7	82.4	75.5
KPI4	80	76.5	78.7
KPI5a	74.4	93.6	84.4
KPI5b	79.1	91.5	85.6
KPI6	77.2	67.6	73.4
KPI7a	76.5	91.3	85
KPI7b	82.4	95.7	90

New teams appear to have better performance in several of the KPIs, in particular recording pretreatment screening (KPI-1) and disease assessments at three and twelve months (KPI-5, KPI-7). These metrics will remain in the revised audit to be introduced next year (see section 6).

The results are not unexpected in that longstanding participants might have lost some of the momentum they had when starting. However, longstanding teams are consistently submitting greater proportions of clinical reviews at three and twelve months – albeit these reviews record fewer disease assessments.

5.2 Time trends in introducing advanced therapies into a patient's treatment

Over the years, the advent of biologic agents has revolutionised the treatment landscape for IBD. These advanced agents, including anti-TNF therapies, have demonstrated efficacy in inducing and maintaining remission, reducing hospitalisations, and averting complications. With continued advancements in research and development, novel biologic agents targeting diverse pathways and mechanisms of action have emerged, thereby expanding the therapeutic repertoire available to patients. Tofacitinib has been included here; although not a biologic, it is the first of a new category of small molecule immunomodulators that have a growing place in the therapy of IBD. The term 'biologic agent' is being replaced by the newer term 'advanced therapy' to better reflect this advance.

We have explored the time from diagnosis to the prescription of various advanced therapies in two cohorts of data submitted to the Registry. The first table (below) presents data where the patient's treatment had begun in the five years up to March 2021. The second table presents data where treatment had begun between April 2021 and March 2022 (the most recent data available). The data for adalimumab and infliximab include the biologic originator and its biosimilars.

Table 3: Time to treatment start of any biologic, where started between April 2016 and March 2021

Characteristic	Adalimumab N = 9,122	Infliximab N = 9,067	Tofacitinib N = 352	Ustekinumab N = 2,175	Vedolizumab N = 4,191
Diagnosis					
CD	6,320 (69%)	5,444 (60%)	8 (2.3%)	1,947 (90%)	1,769 (42%)
UC	2,614 (29%)	3,36 (37%)	328 (93%)	198 (9.1%)	2,305 (55%)
IBDU	188 (2.1%)	256 (2.8%)	16 (4.5%)	30 (1.4%)	117 (2.8%)
Diagnosis to drug start (years)	5 (2 - 13)	4 (1 - 10)	6 (2 - 13)	9 (4 - 17)	7 (3 - 14)

Diagnosis: n (%); Diagnosis to drug start (Years): Median (IQR)

Table 4: Time to treatment start of any biologic, where started between April 2021 and March 2022

Characteristic	Adalimumab N = 1,063	Infliximab N = 902	Tofacitinib N = 66	Ustekinumab N = 522	Vedolizumab N = 712
Diagnosis					
CD	670 (63%)	476 (53%)	0 (0%)	361 (69%)	325 (46%)
UC	345 (32%)	395 (44%)	61 (92%)	152 (29%)	364 (51%)
IBDU	48 (4.5%)	31 (3.4%)	5 (7.6%)	9 (1.7%)	23 (3.2%)
Diagnosis to drug start (years)	5 (1 - 11)	3 (1 - 10)	4 (1 - 11)	8 (3 - 16)	7 (3 - 15)

Diagnosis: n (%); Diagnosis to drug start (Years): Median (IQR)

These tables provide insights into the usage and distribution of advanced therapies among different diagnoses and the time taken from diagnosis to starting each medication. The average time from diagnosis to starting these drugs offers important information on the treatment timeline and patient journey.

Comparing the time from diagnosis to start of drug in the earlier and later cohorts suggests earlier use in a patient's disease course in more recent practice. These figures reflect the time patients typically spend on alternative treatments before starting a particular advanced therapy. As these drugs are the most potent in treating IBD, trends toward their earlier introduction should improve the quality of life of patients whose severity of disease demands these medications.

5.3 IBD team participation

The table below shows, in alphabetical order, all the sites or Trusts who have submitted records to the Registry at any time since 2016. IBD teams who have uploaded also to our new platform (opened in July 2022) are marked in **bold**.

Table 5: IBD teams participating in the IBD Registry, listed by site or Trust name

ADDENBROOKE'S HOSPITAL	NOTTINGHAM UNIVERSITY HOSPITALS NHS TRUST
ALDER HEY CHILDREN'S HOSPITAL	**PRINCESS ALEXANDRA HOSPITAL**
ASHFORD AND ST PETER'S HOSPITALS NHS TRUST	**PRINCESS ROYAL HOSPITAL, SUSSEX**
BARKING, HAVERING AND REDBRIDGE UNIVERSITY HOSPITALS NHS TRUST	QUEEN ALEXANDRA HOSPITAL
BASILDON UNIVERSITY HOSPITAL	QUEEN ELIZABETH HOSPITAL, BIRMINGHAM
BEDFORDSHIRE HOSPITALS NHS FOUNDATION TRUST	QUEEN ELIZABETH HOSPITAL, GATESHEAD
BIRMINGHAM CHILDREN'S HOSPITAL	ROTHERHAM GENERAL HOSPITAL
BRADFORD ROYAL INFIRMARY	ROYAL ALBERT EDWARD INFIRMARY
BRISTOL ROYAL HOSPITAL FOR CHILDREN	ROYAL BERKSHIRE HOSPITAL
BUCKINGHAM HEALTHCARE NHS TRUST	**ROYAL BOLTON HOSPITAL**
CALDERDALE & HUDDERSFIELD NHS FOUNDATION TRUST	ROYAL CORNWALL HOSPITAL
CHESTERFIELD ROYAL HOSPITAL	**ROYAL DERBY HOSPITAL**
COUNTY DURHAM AND DARLINGTON NHS FOUNDATION TRUST	ROYAL DEVON AND EXETER HOSPITAL
DARENT VALLEY HOSPITAL	ROYAL FREE HOSPITAL
DERRIFORD HOSPITAL	ROYAL GLAMORGAN HOSPITAL
DORSET COUNTY HOSPITAL	ROYAL LONDON HOSPITAL
EAST AND NORTH HERTFORDSHIRE NHS TRUST	ROYAL MANCHESTER CHILDREN'S HOSPITAL
EAST KENT HOSPITALS UNIVERSITY NHS FOUNDATION TRUST	ROYAL STOKE UNIVERSITY HOSPITAL
EAST SURREY HOSPITAL	**ROYAL SURREY COUNTY HOSPITAL**
EAST SUSSEX HEALTHCARE NHS TRUST	**ROYAL SUSSEX COUNTY HOSPITAL**
EPSOM HOSPITAL	**ROYAL UNITED HOSPITAL, BATH**
FRIMLEY HEALTH NHS FOUNDATION TRUST	ROYAL WOLVERHAMPTON HOSPITALS NHS TRUST
GEORGE ELIOT HOSPITAL	SALISBURY HOSPITAL
GREAT ORMOND STREET HOSPITAL FOR CHILDREN	SANDWELL AND WEST BIRMINGHAM HOSPITALS NHS TRUST
GREAT WESTERN HOSPITAL	SHEFFIELD CHILDREN'S HOSPITAL
GUY'S HOSPITAL	**SHEFFIELD TEACHING HOSPITALS NHS FOUNDATION TRUST**
HAMPSHIRE HOSPITALS NHS FOUNDATION TRUST	**SHERWOOD FOREST HOSPITALS NHS FOUNDATION TRUST**
HARROGATE DISTRICT HOSPITAL	SHREWSBURY AND TELFORD HOSPITAL NHS TRUST
HEREFORD COUNTY HOSPITAL	**SOMERSET NHS FOUNDATION TRUST**
HILLINGDON HOSPTIAL	**SOUTHAMPTON GENERAL HOSPITAL**
HOMERTON UNIVERSITY HOSPITAL	ST GEORGE'S HOSPITAL

IMPERIAL COLLEGE HEALTHCARE NHS TRUST	ST HELIER HOSPITAL
JAMES PAGET UNIVERSITY HOSPITAL	ST MARY'S HOSPITAL, ISLE OF WIGHT
JENNY LIND CHILDREN'S HOSPITAL	**ST THOMAS' HOSPITAL**
KING'S COLLEGE HOSPITAL NHS FOUNDATION TRUST	STEPPING HILL HOSPITAL
KINGSTON HOSPITAL	**TAMESIDE HOSPITAL**
LEIGHTON HOSPITAL	**TORBAY HOSPITAL**
LEWISHAM AND GREENWICH NHS TRUST	**UNITED LINCOLNSHIRE HOSPITALS NHS TRUST**
LIVERPOOL UNIVERSITY HOSPITALS NHS FOUNDATION TRUST	**UNIVERSITY COLLEGE HOSPITAL**
LONDON NORTH WEST UNIVERSITY HEALTHCARE NHS TRUST	**UNIVERSITY HOSPITAL COVENTRY**
MAIDSTONE AND TUNBRIDGE WELLS NHS TRUST	UNIVERSITY HOSPITAL OF WALES
MANCHESTER ROYAL INFIRMARY	**UNIVERSITY HOSPITALS DORSET NHS FOUNDATION TRUST**
MERSEY AND WEST LANCASHIRE TEACHING HOSPITALS NHS TRUST	**UNIVERSITY HOSPITALS OF MORECAMBE BAY NHS FOUNDATION TRUST**
MILTON KEYNES UNIVERSITY HOSPITAL	**WARRINGTON HOSPITAL**
NEWHAM UNIVERSITY HOSPITAL	**WARWICK HOSPITAL**
NORTH TEES AND HARTLEPOOL NHS FOUNDATION TRUST	**WEST HERTFORDSHIRE TEACHING HOSPITALS NHS TRUST**
NORTH WEST ANGLIA NHS FOUNDATION TRUST	**WEST SUFFOLK HOSPITAL**
NORTHAMPTON GENERAL HOSPITAL	**WHITTINGTON HOSPITAL**
NORTHERN CARE ALLIANCE NHS FOUNDATION TRUST	**WORCESTERSHIRE ACUTE HOSPITALS NHS TRUST**
NORTHERN LINCOLNSHIRE AND GOOLE HOSPITALS NHS FOUNDATION TRUST	WREXHAM MAELOR HOSPITAL

One hundred and three IBD teams have submitted data via our old platform at NHS Digital. In the first year since the move to receiving data directly to our own data submission platform, we are grateful to the 48 IBD teams who have been in the vanguard of uploading via this new platform. We look forward to this number growing as we assist more IBD teams to become familiar with the new dataflow.

6 Revision of the national IBD clinical audit

The IBD Clinical Audit has been under review, led by the BSG IBD Section. The results of this major review, undertaken across 2021 and 2022, including a two-stage Delphi consensus with key stakeholders and the IBD clinical/patient community, has now been formally published in Frontline Gastroenterology[1].

We reproduce here (with permission from the British Medical Journal) the commentary by Professor R Mark Beattie, editor of *Frontline Gastroenterology.*

Establishing key performance indicators for inflammatory bowel disease in the UK

"There have been multiple quality improvement initiatives in Inflammatory Bowel Disease which have led to improvements in clinical care and outcomes. In this paper using stakeholder meetings – including clinicians, professional groups and patients – and then a two stage Delphi process Quraishi and colleagues establish and refine four key performance indicators that can be used to benchmark clinical care within a quality improvement framework. The methodology is detailed in the paper including the methodology for national implementation. The key performance indicators include

- Time from primary care referral to diagnosis in secondary care
- Time to treatment recommendation following a diagnosis
- Appropriate use of steroids
- Advanced therapies prescreening and assessment

The authors discuss each in detail. The Delphi consensus reported >85% agreement on feasibility of local adoption of the QI process and >75% agreement on the utility of benchmarking of the KPIs. These KPIs can be used for benchmarking to improve and reduce the individual variation in IBD care across the UK."

6.1 Updating the biologic KPIs

A summary of the changes that are being introduced is given here. The longstanding assessment of the supervision of courses of biological therapies is retained in the revised audit, but with some important changes:

6.1.1 More drugs included

The medications included in the audit will be expanded to small molecule immunomodulators, as well as the existing focus on biological agents. The term advanced therapies is now being used to encompass these medications.

6.1.2 More courses of treatment included

All courses of advanced therapies will now be included in analyses, whereas records eligible for analysis in the previous national audit were restricted to the first biologic received by a patient.

6.1.3 More up to date treatment courses

The existing audit analysed treatments commenced after April 2016. The revised audit will include treatments with advanced therapies started in 2021 or later.

6.1.4 Assessment of safety added

For the three- and twelve-month reviews after starting an advanced therapy, the clinical team will be asked to confirm that assessments of efficacy and safety have been carried out. Previously, only assessment of disease activity was required.

6.1.5 Likely impact of changes to biologic KPIs

The move from auditing only the first biologic treatment a patient receives to the inclusion of all courses of advanced therapies will greatly increase the number of treatment courses available for analysis. To gauge the likely uplift in records available, we have re-analysed data received in the last two years to examine the numerical impact of this change.

Table 6: numerical difference of change in method

	Count
Eligible records including **first** starts only	2861
Eligible records including **all** starts	4055

Although the table above reports only biologic starts (as opposed to the broader advanced therapies category envisaged for the revised audit), this analysis shows there will be >40% more records available for analysis in the revised audit.

In addition, bringing the start point of included records to January 2021 (rather than April 2016 in the existing audit) means the audit will better reflect current prescribing, and the results will have greater potential to influence the practice of IBD teams.

6.2 Time to diagnosis and treatment

The time taken to diagnose IBD, particularly Crohn's disease, is often many months and can be more than a year[2].The new national audit will include a Key Performance Indicator addressing this. It is intended that IBD teams collect prospective data on all newly diagnosed patients. The audit will measure:

- Date of referral from primary care
- Date of documentation in the clinical record of a confirmed diagnosis of IBD

6.3 Use of corticosteroids

In the realm of IBD, the utilisation of corticosteroids has raised concerns due to their adverse impact on both the quality of life and long-term outcomes. Aligning with this concern, a KPI focusing on steroid use has been discussed and validated as part of the KPIs review, and now takes its place within the revised national clinical audit.

The prime objective of this steroid use KPI is to assess the utilisation of steroids within individual IBD services, shifting the focus from simple steroid excess. It is well-established that repeated courses of steroids in the absence of appropriate maintenance therapy are indicative of suboptimal care. We have examined the routine information on steroid use that IBD teams have submitted to the Registry, in anticipation of the introduction of the steroid use KPI.

The plot below shows, for the twenty IBD teams that have provided the greatest number of courses of steroid treatment, the length in weeks of steroid courses given by mouth. Courses lasting longer than one year have been excluded. The two vertical red lines represent course durations of 8 and 12 weeks. Each data point represents a course length, with the box showing the median and interquartile range. The national aggregate data for all IBD teams is shown on the lower panel.

Figure 2: heatmap/box-and-whisker plot for duration of steroid treatment, for 20 IBD team at a hospital site

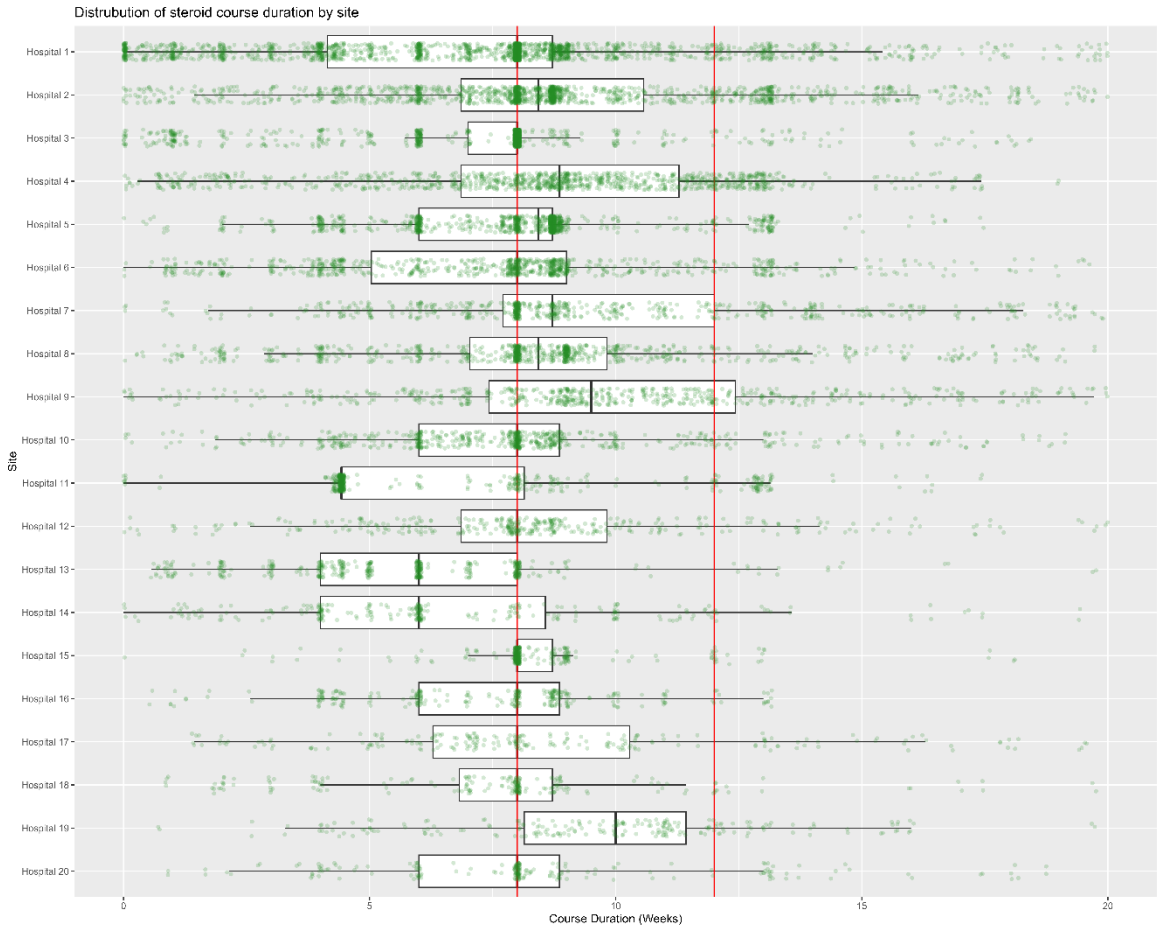
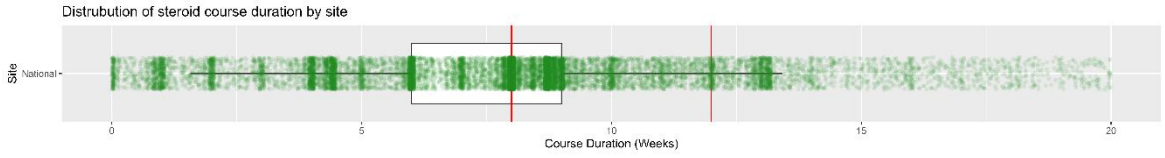


Figure 3: heatmap/box-and-whisker plot for duration of steroid treatment, aggregated across all submitting IBD hospital sites



Records of courses by mouth of prednisolone, budesonide and Clipper are included. It is noteworthy that the duration of steroid usage for most IBD teams accords with recommended guidance. This adherence to the prescribed guidelines reflects a commitment to achieve optimal patient care and treatment outcomes.

By exploring local steroid usage, IBD services are empowered to develop innovative initiatives such as the establishment of rapid access flare clinics, proactive disease control measures, patient empowerment programs, and the prompt initiation and optimization of maintenance therapies. This KPI serves as a catalyst for the evaluation of steroid usage, with the ultimate goal of enhanced overall management of IBD.

7 Implementing the revised national clinical audit

7.1 Updating the Registry dataset

The revisions to the audit required a small number of additional data items to be included in the Registry dataset to capture all the data for calculating the new KPIs. These items were added in 2021 and 2022 as the IBD section of the British Society of Gastroenterology evolved a consensus on the new measures. The Registry holds the data it receives in a research database approved by the Health Research Authority. Renewed approval has been received for Registry dataset 2022_L.

7.2 Data capture approach and tools

The Registry has a flexi-tool approach to data capture: rather than prescribe a mandatory specific tool to use, we seek to re-use data already in the many hospital IT systems that IBD teams use to record clinical information used in the care of their patients – be it hospital-wide electronic patient record (EPR), bespoke IBD system or the Registry's own online WebTool. The goal is to reduce the amount of clinical time required in data entry.

7.2.1 Existing hospital systems

There are now a number of different hospital IT systems with which the IBD Registry data standard has been successfully integrated, allowing the direct collection of clinical data. We will be working with these teams to help them in adjusting their systems to reflect the capture of the revised data items for the new KPIs.

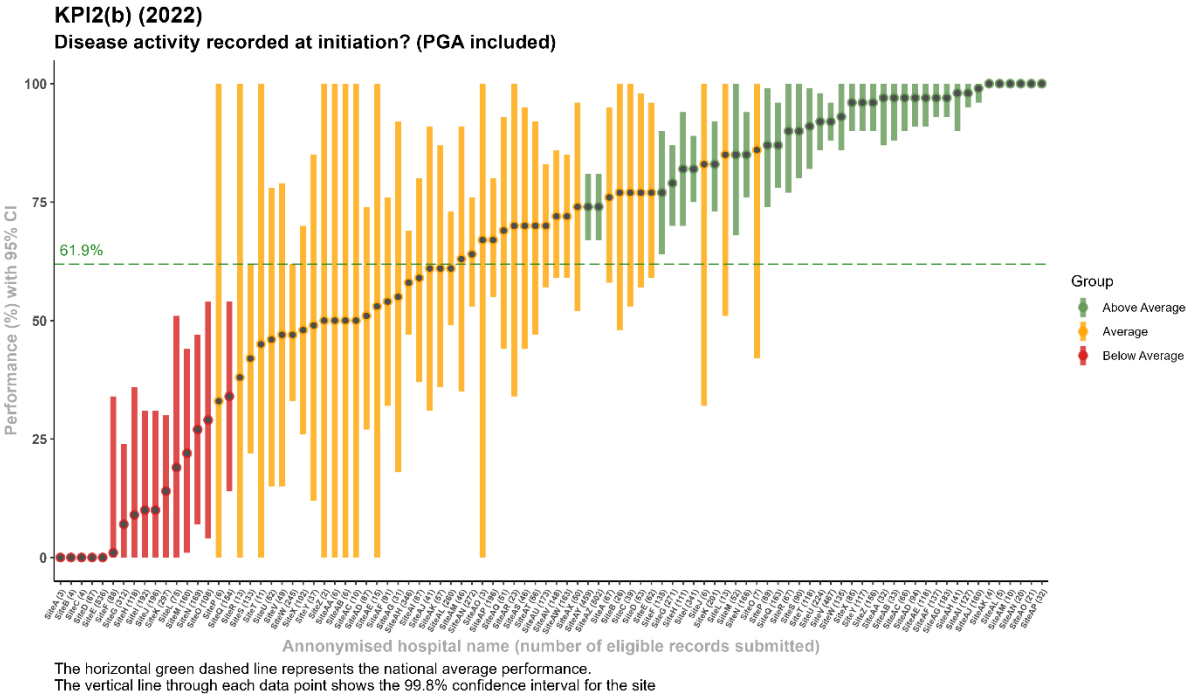
7.2.2 New data capture tool

Despite the increasing take-up of hospital-wide EPRs, some IBD teams only have available local spreadsheets, which can be insecure, and which may fail to capture data in consistent formats. Identifying this gap, and also being aware of the need for specific data to be recorded for the calculation of the new KPIs, the IBD Registry has developed a cloud-based data entry tool on our REDCap platform that will be available at no charge to IBD teams who have no other means of collecting data for the national clinical audit.

7.3 Updated presentation of KPIs

For some years the Registry has used funnel plots to present back to clinical teams their performance in the national audit. The virtue of funnel plots is that they enable data to be presented with reference to the number of records a team has submitted, But the complexity of the plots can make it difficult for the less experienced reader to interpret. With the opportunity provided by the transition to the new KPIs we shall investigate the usefulness of reporting data as caterpillar plots, which are both familiar to many and may support easier assimilation of results.

Figure 4: RAG-coded caterpillar plot of KPI2(b) disease activity recorded at initiation



The plot above shows the same data as in the funnel plot in section 5, with each datapoint representing the mean performance for a IBD team and the vertical bar representing the 99.8% confidence interval. Where confidence intervals overlap with the national mean, sites should consider themselves to have performance matching the national average. We believe presenting KPIs in this way enables teams easily to see their performance in relation to the national average, with the additional benefit of a RAG rating categorising their performance.

7.4 Receiving records from participating teams

Changing the receipt of records to our own data submission platform gives us the ability to receive data from all UK nations; to grow, where the patient has consented, an identifiable database; as well as providing agility in updating our dataset. The downside has been the records of patients who provided consent to our previous dataflow (via NHS Digital) cannot flow to our own submission platform because their consent explicitly referred to NHS Digital. To overcome this, we have been very active in bringing the new dataflow to the attention of people with IBD and encouraging them to give consent to this dataflow.

Additionally, affecting England only, the national data opt out became mandatory in 2022. To enable teams to submit only correctly permissioned records, we have provided a simple desktop tool that carries out the necessary removal of records as a pre-step to uploading records to our platform. In the twelve months since these changes were introduced, records submitted are already more than a quarter the number received during the previous eight years.

7.5 Data completeness

An unanticipated but welcome benefit of the new dataflow has been an improvement in the completeness of information in each record. The two UpSet plots below show how often three crucial influences on treatment outcomes are provided together in the records we receive.

Figure 5: Overlap of gender, eligible diagnosis, and eligible disease location in records received via NHS Digital from 2015 to 2022.

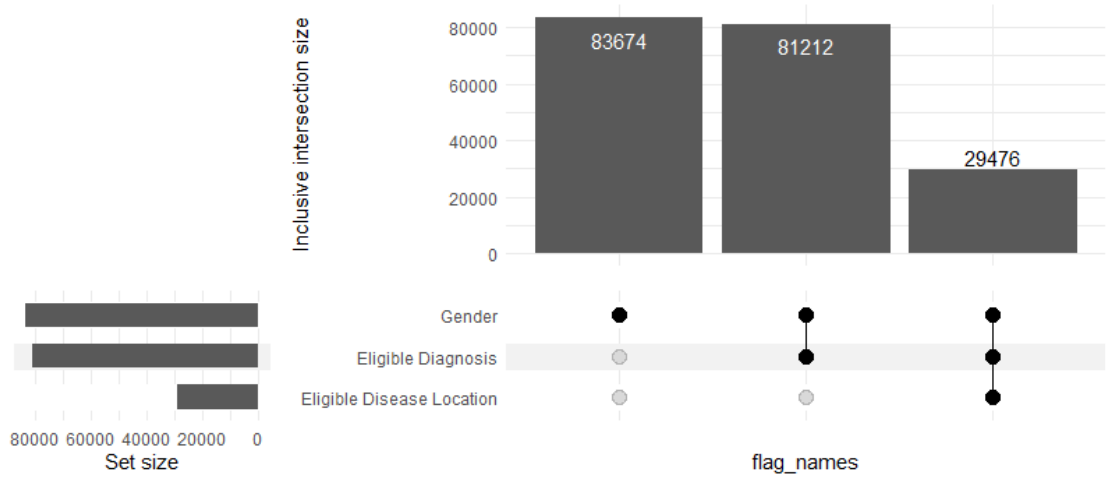
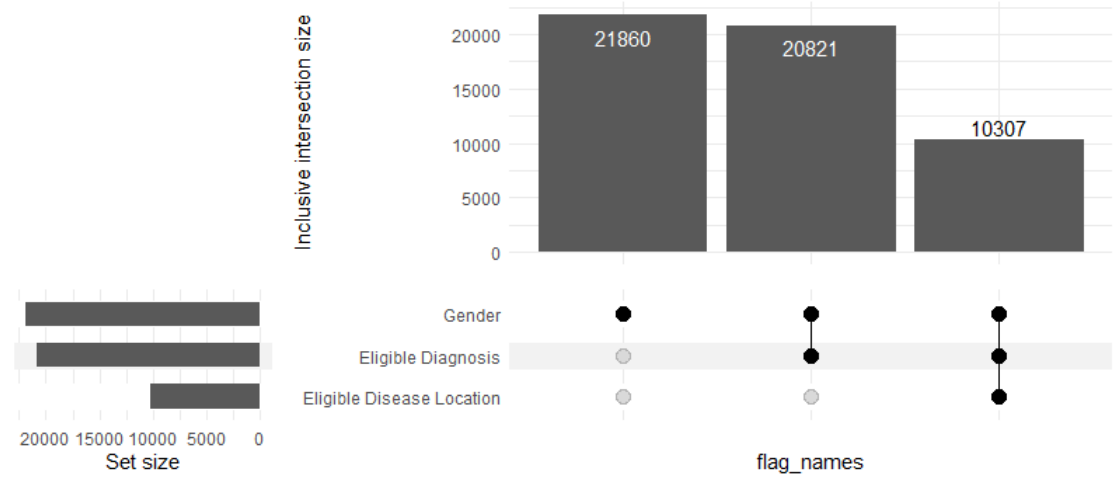


Figure 6: Overlap of gender, eligible diagnosis, and eligible disease location in records received via Registry's own submission platform during 2023.



”Completeness”, assessed in this way, is present in 47% of records submitted to our new platform, whereas completeness was present only in 35% of records submitted via NHS Digital. This improvement reflects the increasing understanding of participating teams of the value of more complete data for quality improvement and for research.

7.6 Concluding notes

The IBD Registry’s priority continues to be the support of Quality Improvement programmes of IBD teams throughout the UK. Our main focus has been to assist teams in data delivery while the transition of the national IBD Clinical Audit is taking place. We have continued quarterly reporting of IBD teams’ data and, in addition, have been reviewing ways to receive the data for analysis of the new KPIs by updating our dataset and the development of a new online tool.

8 About the IBD Registry

8.1 Purpose, Structure and Governance

The purpose of the IBD Registry is to improve understanding of the treatment and care of people with IBD and to facilitate research by the collection and analysis of clinical and patient-provided data. We are a not-for-profit organisation wholly owned by the British Society for Gastroenterology, the Royal College of Physicians and Crohn’s & Colitis UK.

The IBD Registry is formed as a company limited by guarantee (i.e. without any shares). We are registered in England and Wales with company number 11197749. Our registered address as 1 St Andrews Place, Regent’s Park, London, NW1 4LB

9 Citation and correspondence

9.1 Citation

If you wish to cite analysis from this report, please use the following citation:

UK IBD Registry. Biological Therapies Annual Report (2023). London: UK IBD Registry Ltd, 2023.

9.2 Contact and Correspondence

Our website has further information on our work on quality improvement and on participation in the IBD National Clinical Audit. If you still have questions, please contact us as follows:

- If you are an IBD clinical team with an enquiry about participation in the national clinical audit, please contact us on support@ibdregistry.org.uk
- If you have an enquiry about undertaking an IBD quality improvement study or research, please contact us on analysis@ibdregistry.org.uk

If you have a postal enquiry, our office address is: 1 St Andrews Place, Regent's Park, London, NW1 4LB

References:

1. Quraishi MN, Dobson E, Ainley R *et al*, Establishing key performance indicators for inflammatory bowel disease in the UK. Frontline Gastroenterology 2023; **14**: 407-414
2. Jayasooriya N, Baillie S, Blackwell J *et al.* Systematic review with meta-analysis: Time to diagnosis and the impact of delayed diagnosis on clinical outcomes in inflammatory bowel disease. Aliment Pharmacol Ther 2023; **57**: 635-652