IBD Biological Therapies Audit

Annual Report 2021

July 2021

1 Foreword

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

Monitoring benchmarked clinical aspects of care delivery is a fundamental component of understanding the quality of care of people with IBD. Biological therapies are known to have the potential to be transformational to patient outcomes but require close monitoring of their use against established clinical guidelines for patient safety and best response.

This rolling assessment of how IBD teams are delivering biological treatments provides an invaluable piece of the picture. Taken overall, the Key Performance Indicators (KPIs) tracked show stable performance of IBD teams despite COVID-19.

The number of IBD teams submitting data continues to grow, with the total number of patient-level records available for reporting the biologics KPIs now at 8,552 (the total number of records we hold is 75,172)

I suspect all clinical colleagues will agree that the past year with COVID-19 has been a challenging one, and so the continued participation and focus from IBD teams across the country on tracking their biologics care pathways and outcomes for patients deserves both high recognition and thanks.

Prof Stuart Bloom

Medical Director, IBD Registry

2 Summary

Inflammatory bowel disease is life long and incurable and estimated to affect over 500,000 people in UK.[1] The effectiveness of treatment leapt forward with the introduction of biological agents more than twenty years ago. The variety of biological agents continues to grow, presenting challenges to IBD teams in maintaining their knowledge of newer agents and providing safe care.

To support the delivery of safe, effective use of biological agents, the national audit of biological therapies in IBD was begun in 2006 under the auspices of the Royal College of Physicians, supported by the Healthcare Quality Improvement Partnership (HQIP). The clinical audit transitioned to the UK IBD Registry in 2017, with IBD being included in NHS England's Quality Accounts and the Registry formally recognised as provider.

In the same year we were founder members of IBD UK, an alliance of 17 professional bodies, royal colleges and patient organisations. As part of IBD UK, we worked to develop the revised IBD Standards 2019, which includes a standard for biological therapies, and to submit the IBD Audit for inclusion in Quality Accounts.

The rolling IBD Biological Therapies Audit reported here is the clinical element of the combined IBD audit and is complemented by the IBD Service Standards, which adds the organisational element of the full IBD Audit. Trusts providing care for adult or paediatric patients are encouraged to participate fully by submitting both clinical and organisational data to complete the two complementary workstreams.

Agreed protocols should be in place for pre-treatment tests, vaccinations, prescribing, administration and monitoring of immunomodulator and biological therapies.

Statement 1.12

ibduk.org/ibd-standards

[1] Ghosh, N., & Premchand, P. (2015). A UK cost of care model for inflammatory bowel disease. *Frontline Gastroenterol*, 6(3):169-174

IBD Registry

Contents

Acknowledgements

This work is based on analysis of patient data held by the IBD Registry. We thank all the participating IBD hospital teams for their help and support for the Registry 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 gratefully acknowledge Prof Stuart Bloom, Dr Keith Bodger, Dr Fraser Cummings and Dr Nick Kennedy for the clinical oversight provided for these reports, together with Liz Dobson and Dr Stephen Grainger for the operational and clinical management of the production of the report.

We would also like to acknowledge and thank the IBD Registry team involved in the analysis, production and distribution of these reports: David Fretwell, Sarah Miles and Fred Taylor.

Finally we would also like to thank the Crohn's & Colitis team who support IBD UK together with the BSG IBD Section members who have provided input and liaison for this report and throughout the quality accounts year.

3 Reading this report

This report has been written primarily for a clinical readership, but to make it more informative for the general reader we have added endnotes to explain key terms. We hope in this way that the report will be accessible to patients and clinicians alike.

Biological agents are treatments used for Crohn's disease and ulcerative colitis (the two main forms of IBD). More information about these is available from the charity Crohn's & Colitis UK.

HQIP is an independent organisation led by the Academy of Medical Royal Colleges, the Royal College of Nursing and National Voices. HQIP's purpose is to influence and improve healthcare at all levels.

4 Biological Therapies Clinical Audit

4.1 Definition

The Registry has developed and maintains the KPIs for the National Audit of Biological Therapies (now part of Quality Accounts). These clinical KPIs track the improvement in biologics treatment of patients and are presented as a cumulative audit of biological treatments since 2016.

The scope, purpose and guide to the KPI definitions are all available on our website. A diagrammatic summary is given below.

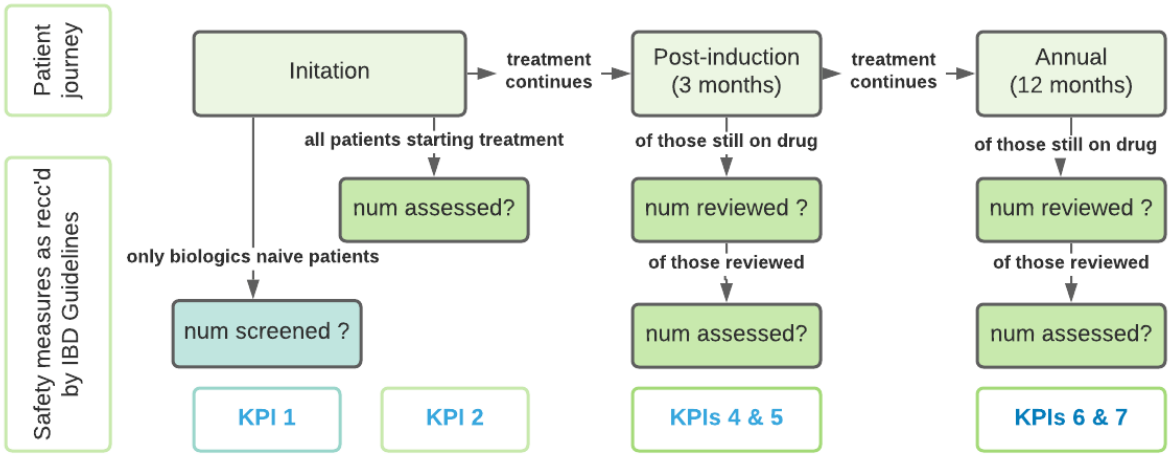


Diagram: the six clinical KPIs for monitoring quality of care in treatment using biological therapy (see Guide for details)

KPI 3 (not shown in this schematic) refers to the collection of Registry consent – a critical element for audit as we move towards a fully-consented model with maximum transparency and choice for patients on use of their health data.

4.2 Local Reports to IBD teams

This report is the national summary of the clinical audit performance, published annually. It is a summary of the analysed data that we present back to IBD clinical teams.

Each participating team receives individual reports, presenting their cumulative performance against the national benchmark, to support them in their local quality of care monitoring and tracking.

Last year we published reports for each team every quarter, with each report containing 1,250 datapoints. Participating teams were able to review their local statistics against the national figures.

4.3 Criteria for inclusion

NHS Trusts and Health Boards providing care for adult or paediatric patients in UK diagnosed with IBD: Crohn's disease, ulcerative colitis or IBD-Unspecified (ICD-10 Codes K50, K51 and K52 respectively)

4.4 KPI Performance

We have compared the cumulative performance, as at each year, for the past 3 years.

	Cumulative to Jan 2019	Cumulative to Jan 2020	Cumulative to Jan 2021	Trend
Cumulative total of adult patients eligible for audit	4,174	6,411	8,315	
KPI 1: Complete pre-treatment screening	69%	71%	74%	
KPI 2: Disease activity assessment at initiation (PGA included)	63%	67%	64%	
KPI 3: Registry consent	44%	45%	46%	
KPI 4: Review at 3 months	39%	41%	41%	
KPI 5: Disease activity assessment recorded of those reviewed at 3 months (PGA included)	62%	64%	62%	
KPI 6: Review at 12 months	33%	36%	35%	
KPI 7: Disease activity assessment recorded of those reviewed at 12 months (PGA included)	60%	67%	61%	

There has been an approximate doubling of records assessable for reporting in the audit in the last two years, with no discernible slowing of submission of records due to COVID-19.

Over this time, performance of the KPIs has been stable - attesting to continued attention to good practice in very difficult circumstances.

Nonetheless, we urge IBD teams to address the shortfall in recording reviews and disease assessments at all points in the patient's biologics pathway.

We are also investigating whether the weight of early records (when biological treatments were novel and less well established) is obscuring more recent changes in performance.

The clinical audit has been running cumulatively since 2016, and the need to review this and look to re-baseline it is recognised. In the later section (7.1), we present a high level look at the effect of rebaselining to start from 2018.

4.5 First biological agent

The table reports a patient level analysis of the first biologic initiation since April 2016 for all the adult records we hold. The data available is greater than that assessable for the audit KPIs, which require a clinical review also to have been reported at the time of the biologic initiation. Cumulative cases up to January 2021 are reported.

Patients who switched (stopped one biologic and started another) are included only once.

	Crohn's Disease		Ulcerative Colitis		IBDU	
Biologic Agent	n	%	n	%	n	%
Remicade	235	2.5%	140	2.6%	3	< 1%
Remsima	1731	18.2%	1116	20.5%	59	18.2%
Inflectra	1300	13.6%	906	16.7%	88	27.2%
Flixabi	107	1.1%	100	1.8%	3	< 1%
Zessly	85	< 1%	65	1.2%	5	1.5%
Golimumab	22	< 1%	221	4.1%	4	1.2%
Humira	3034	31.8%	1109	20.4%	66	20.4%
Imraldi	686	7.2%	280	5.1%	27	8.3%
Amgevita	390	4.1%	135	2.5%	9	2.8%
Hyrimoz	241	2.5%	119	2.2%	4	1.2%
Idacio	28	< 1%	16	< 1%	0	< 1%
Cyltezo	0	< 1%	0	< 1%	0	< 1%
Hulio	0	< 1%	0	< 1%	0	< 1%
Certolizumab	3	< 1%	0	< 1%	0	< 1%
Vedolizumab	974	10.2%	1200	22.1%	50	15.4%
Ustekinumab	692	7.3%	31	< 1%	6	1.9%
Total	9528	(100%)	5438	(100%)	324	(100%)

Key to the table:

Colours in the table above group the biological agents by their biologic originator (given at the top of each colour group).

Agents on a white background have no biosimilars.

5 Quality Improvement in IBD

5.1 IBD Standards

These clinical KPIs originated from the RCP IBD Audit, and have been maintained with transition to the Registry. The Registry was closely involved in the development of the IBD Standards defined in 2019 and have ensured that the clinical KPIs are in alignment with these.

5.2 Quality Accounts (NHS England)

IBD Audit is listed on Quality Accounts, based on the IBD Standards.

The rolling IBD Biological Therapies Audit is the clinical audit element of the full IBD Audit and is complemented by the IBD Service Standards, which adds the organisational element of IBD Quality Improvement. Trusts are encouraged to participate fully by submitting both clinical and organisational data to complete the two complementary workstreams.

The value the UK IBD Registry adds is to enable ongoing data collection and provide analysis, which results in a growing picture of the longitudinal care of people with IBD. This information allows us to support IBD clinical teams in their continuing work to improve the quality of clinical care.

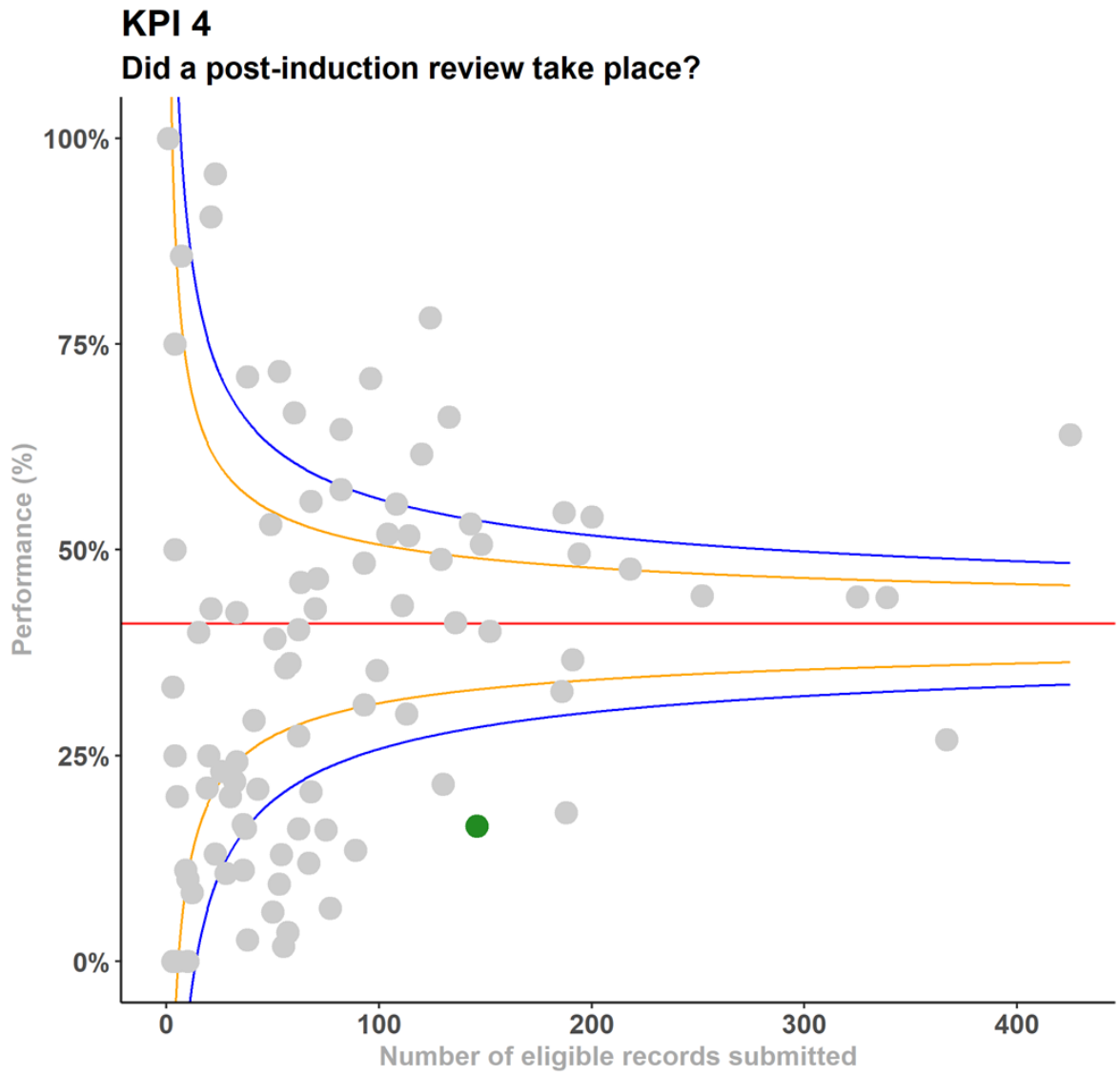
6 KPI reporting methods

Using the defined Key Performance Indicators (KPIs) of the annual biologics audit, we report to each participating IBD team on an ongoing basis (currently quarterly) their local performance.

To improve the information we provide to clinical teams, we are exploring better ways of displaying a site's key data.

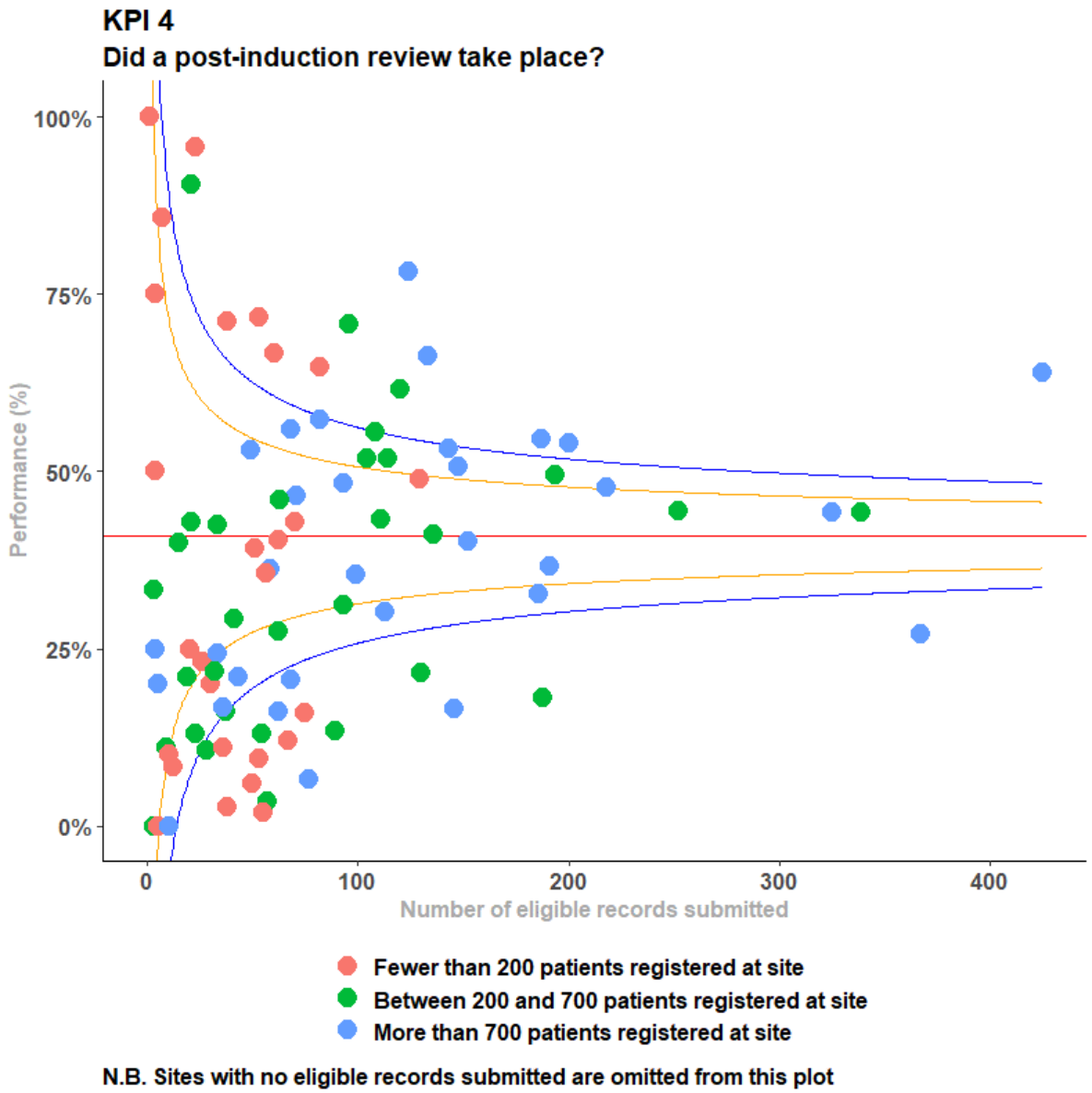
We now produce for each team funnel plots identifying their site amongst all other (anonymised) participating sites. Yellow and blue lines represent upper and lower control limits (yellow 95%; blue 99.8% - roughly equating to ±2 and ±3 standard deviations from the mean) around a centre red line of average performance across all sites.

Sites located below the lower blue control limit are potential outliers and appear to have significantly lower performance than average (as indicated by the green dot below). Charted in this way makes it easy for an IBD team quickly to visualise and compare their performance and to identify areas that might warrant improvement.



The reporting of the KPIs is intended to influence and improve the quality of care patients receive, but there are other factors that affect a site's performance in the audit aside from the quality of care – such as: the ability of sites to submit complete records; the data collection tools in use; the number of clinical and administrative staff; and the differential impact on IBD services of external events such as COVID-19. When considering potentially poor performance all these facets of a service need to be taken into account.

Funnel plots also allow us to visualise trends in KPI performance over time and to investigate other factors that might affect performance, such as the way that an IBD team captures its data or the size of its population. The illustration below shows the performance of sites broken down by the number of records submitted to the Registry:

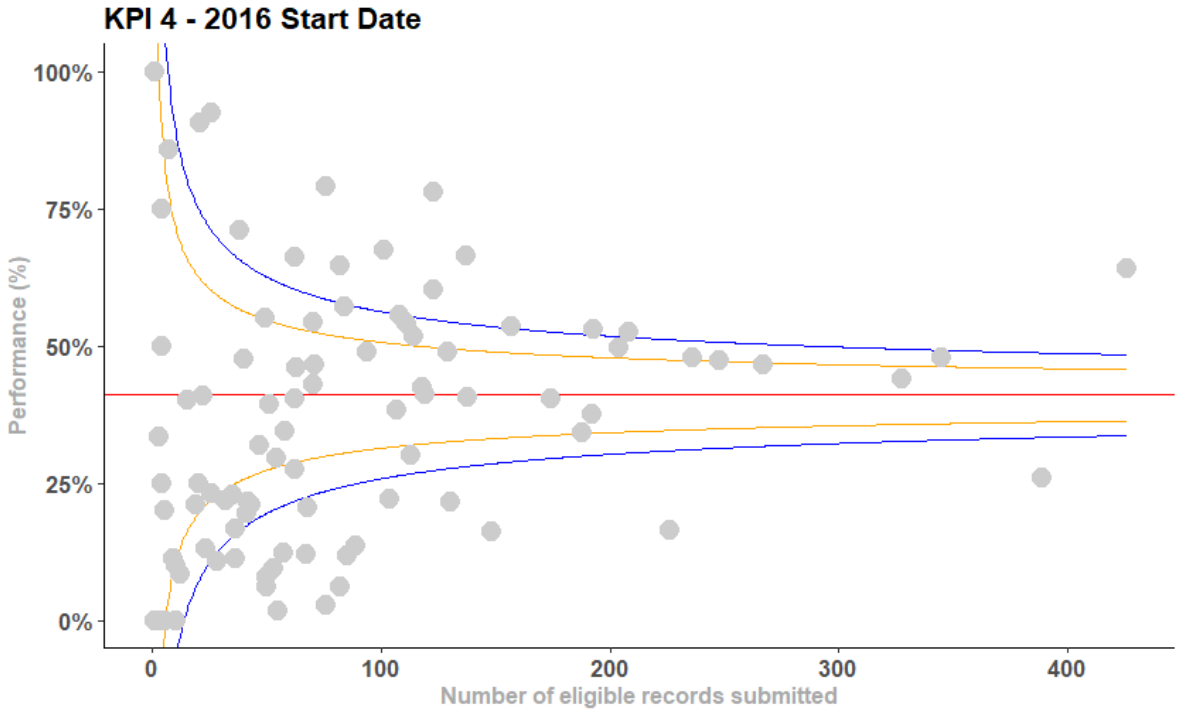


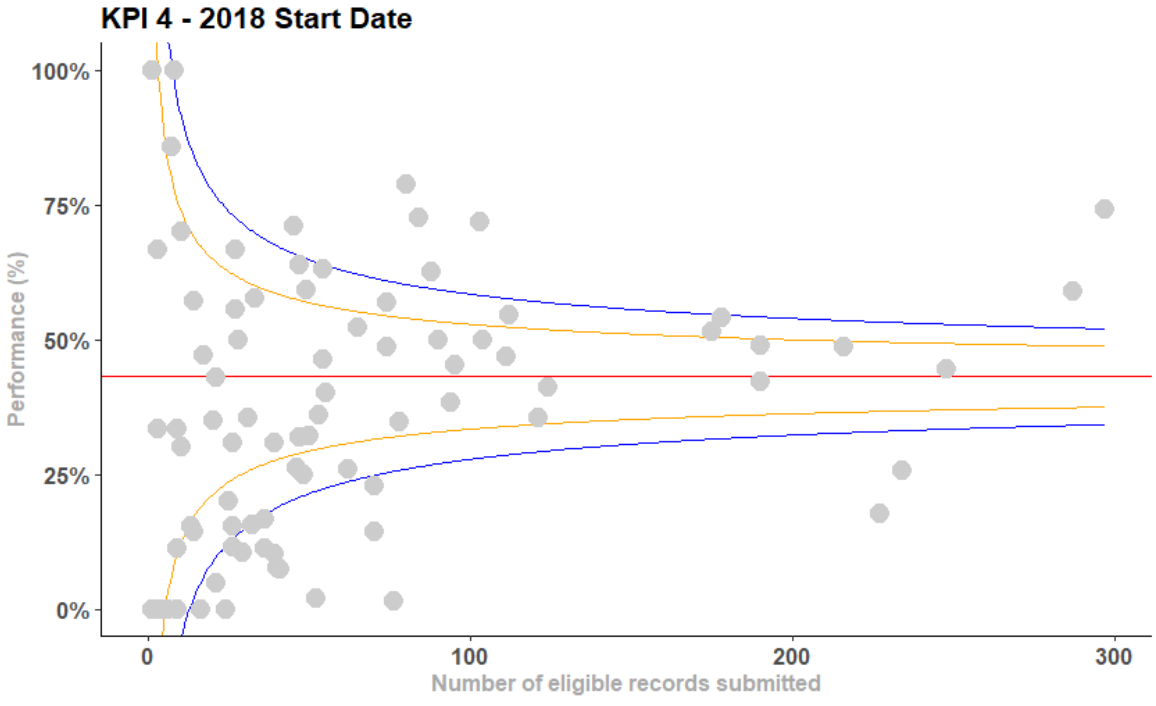
This example shows performance on this audit measure is not obviously associated with the size of the local registered population (roughly equal numbers of the three categories appear within and outside the control limits). It also suggests that some sites particularly focus their data capture activities on cases treated with biological agents (numbers of records eligible for the audit approaching half of all records submitted by the site).

7 Developments in analysis

7.1 Changing first drug start date

We are exploring changing the date from which first biologics are counted in the audit, to correct for legacy data, which might obscure improvements in performance. The figures below plot each site's performance in KPI 4 using either a 2016 and 2018 start date, with cumulative data up to April 2021:





The biologics audit has always analysed and reported cumulative statistics. By focusing reporting of the audit KPIs on a more recent start date (in this example 2018 rather than 2016), the KPIs reflect more up to date behaviour of IBD teams in adhering to best practice, rather than performance being 'held back' by possible previous less good adherence to guidelines.

Compared with first biologics initiated 2016-2021, the funnel plot shows fewer sites falling below the lower control limit (implying poor performance) when only more recent data (2018-2021) is analysed.

8 Site Participation

The table below shows, in alphabetical order, all the sites who have submitted records to the Registry at any time since 2016:

ADDENBROOKE'S HOSPITAL	QUEEN ELIZABETH HOSPITAL BIRMINGHAM
ALDER HEY CHILDREN'S NHS FOUNDATION TRUST	ROYAL ALBERT EDWARD INFIRMARY
ASHFORD & ST PETERS	ROYAL BERKSHIRE HOSPITAL
BASILDON HOSPITAL	ROYAL BOLTON HOSPITAL
BEDFORD HOSPITAL	ROYAL BOURNEMOUTH GENERAL HOSPITAL
BIRMINGHAM CHILDREN'S HOSPITAL	ROYAL CORNWALL HOSPITAL
BRADFORD ROYAL INFIRMARY	ROYAL DERBY HOSPITAL
BUCKINGHAM HEALTHCARE TRUST	ROYAL DEVON AND EXETER HOSPITAL
CALDERDALE & HUDDERSFIELD NHS FOUNDATION TRUST	ROYAL FREE HOSPITAL
CHESTERFIELD ROYAL HOSPITAL	ROYAL GLAMORGAN HOSPITAL
DARENT VALLEY HOSPITAL	ROYAL LONDON HOSPITAL
DARLINGTON MEMORIAL HOSPITAL	ROYAL MANCHESTER CHILDREN'S HOSPITAL
DERRIFORD HOSPITAL	ROYAL SHREWSBURY HOSPITAL
DIANA, PRINCESS OF WALES HOSPITAL	ROYAL STOKE UNIVERSITY HOSPITAL
DORSET COUNTY HOSPITAL	ROYAL SURREY COUNTY HOSPITAL
EAST KENT HOSPITALS UNIVERSITY NHS FOUNDATION TRUST	ROYAL SUSSEX COUNTY HOSPITAL
EAST SURREY HOSPITAL	ROYAL UNITED HOSPITAL
EAST SUSSEX HEALTHCARE NHS TRUST HQ	SALISBURY HOSPITAL
EPSOM HOSPITAL	SANDWELL & WEST BIRMINGHAM HOSPITAL
FRIMLEY PARK HOSPITAL	SCUNTHORPE GENERAL HOSPITAL
FURNESS GENERAL HOSPITAL	SHEFFIELD CHILDREN'S HOSPITAL NHS TRUST
GEORGE ELIOT HOSPITAL	SHEFFIELD TEACHING HOSPITALS
GREAT ORMOND STREET HOSPITAL CENTRAL LONDON SITE	SHERWOOD FOREST HOSPITALS NHS FOUNDATION TRUST
GUY'S & ST THOMAS	SOUTHAMPTON GENERAL HOSPITAL
HAMPSHIRE HOSPITAL	SOUTHPORT GENERAL INFIRMARY
HARROGATE & DISTRICT NHS FOUNDATION TRUST	ST GEORGE'S HOSPITAL
HEREFORD COUNTY HOSPITAL	ST HELIER HOSPITAL
HILLINGDON HOSPTIAL	ST MARY'S HOSPITAL (ISLE OF WIGHT)
HINCHINGBROOKE HOSPITAL	STOCKPORT NHS FOUNDATION TRUST
HOMERTON UNIVERSITY HOSPITAL	TAMESIDE GENERAL HOSPITAL
IMPERIAL COLLEGE	THE GREAT WESTERN HOSPITAL
JAMES PAGET HOSPITAL	THE PENNINE ACUTE HOSPITALS NHS TRUST
KING GEORGE/QUEEN'S BHRUT	THE ROTHERHAM NHS FOUNDATION TRUST
KING'S COLLEGE LONDON	THE ROYAL LIVERPOOL UNIVERSITY HOSPITAL
KINGSTON HOSPITAL	THE WHITTINGTON HOSPITAL
LEIGHTON HOSPITAL	TORBAY HOSPITAL
LISTER HOSPITAL	TUNBRIDGE WELLS HOSPITAL

LONDON NORTH WEST TRUST	UNIVERSITY COLLEGE LONDON HOSPITALS NHS FOUNDATION TRUST
LUTON AND DUNSTABLE HOSPITAL NHS FOUNDATION TRUST	UNIVERSITY HOSPITAL (COVENTRY)
MANCHESTER ROYAL INFIRMARY	UNIVERSITY HOSPITAL AINTREE
MILTON KEYNES UNIVERSITY HOSPITAL	UNIVERSITY HOSPITAL LEWISHAM
MUSGROVE PARK HOSPITAL	UNIVERSITY HOSPITAL OF WALES
NEW CROSS HOSPITAL (WOLVERHAMPTON)	WARRINGTON DISTRICT GENERAL HOSPITAL
NORFOLK AND NORWICH UNIVERSITY HOSPITAL	WARWICK HOSPITAL
NORTHAMPTON GENERAL HOSPITAL (ACUTE)	WATFORD GENERAL HOSPITAL
NOTTINGHAM UNIVERSITY HOSPITALS	WEST SUFFOLK HOSPITAL
PETERBOROUGH CITY HOSPITAL	WEXHAM PARK HOSPITAL
POOLE GENERAL HOSPITAL	WHISTON HOSPITAL
PRINCESS ALEXANDRA HOSPITAL NHS TRUST	WORCESTERSHIRE ACUTE HOSPITALS NHS TRUST
QUEEN ALEXANDRA HOSPITAL	WREXHAM MAELOR HOSPITAL
QUEEN ELIZABETH HOSPITAL	YEOVIL DISTRICT HOSPITAL

8.1 Cumulative Submission

The audit analyses cumulative data from April 2016. IBD teams are asked to submit new cases every quarter, but if a quarter is missed, the cumulative review means that missing cases can be submitted in the next quarter.

	Cumulative to Jan 2019	Cumulative to Jan 2020	Cumulative to Jan 2021
Number of IBD teams participating in the IBD Registry	74	92	102

9 Growth and maturation of the UK IBD Registry

The IBD Registry as an organisation has matured and grown alongside our healthcare records, enabling us to fulfil our purpose more effectively:

- Being more responsive to questions from participating teams
- Being more agile in our analysis of the data we receive
- Providing deeper insights about the delivery of care as our dataset matures
- Informing research and using data we hold to support quality improvement initiatives of the British Society of Gastroenterology and IBD UK

9.1 Growth in hospital sites across the UK

The Registry began nearly a decade ago in 2013 and has grown in stature, breadth of participating IBD teams and records held.

We now have 102 IBD teams submitting data to the Registry, with 91 teams participating in the national audit. This is an increase in 19 IBD teams since our first report in 2019. We have separated out adult records from paediatric records as we report these separately to the relevant teams.

In 2020, the number of IBD teams interacting with us increased as we made the COVID-19 Risk Tool available to patients and clinical teams alike.

Since April 2020, over 118 IBD teams have worked with us to receive the COVID-19 risk data entered by their patients.

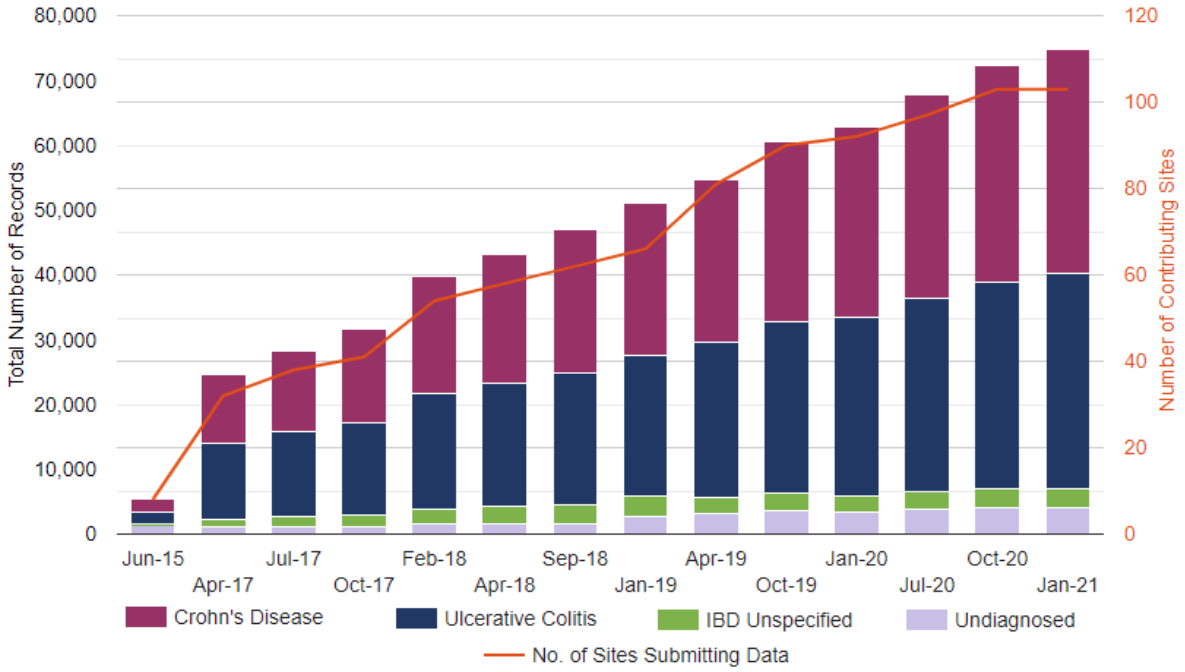
We hope that many of these teams will now look to join us in supporting one of our key goals by submitting data to the biologics audit.

Our next task, and current work in progress, is in reworking our data submission platform so that we can accept data from IBD teams in Northern Ireland and Scotland. These devolved nations have different systems which need to be specially handled. This will allow the IBD teams from these countries to submit to the Registry and participate in the National IBD Biologics Audit.

9.2 Growth in records held

At Jan 2021, the number of patient level records held by the IBD Registry was 75,172. This is an increase of 11,991 records since Jan 2020, and 24,186 since our last report in 2019.

We are pleased to be able to report that the growth of new IBD records has been maintained over time.



All our records hold the current IBD diagnosis of the patient, and so we are able to review our data with separate foci on patients with Crohn's disease and those with ulcerative colitis.

Compared with the proportions of people in the UK with ulcerative colitis and Crohn's disease, records submitted to our Registry show a slight excess of patients with Crohn's disease, probably reflecting the greater disease burden of Crohn's disease, requiring more clinical contacts and the greater use of more potent drugs, particularly biologics, which have been the focus of the national audit for the last decade.

10 Demographics

10.1 Key demographic data

A recent study of IBD in UK primary care reported a stable rate of new cases between 2006 and 2016, with a rising number of patients living with IBD, probably due to IBD being a chronic condition associated with low mortality, despite having a significant and often long-term impact on quality of life.[2]

The table below shows the demographic changes in the IBD population held by the Registry submitted by adult and paediatric IBD teams in secondary care in January 2019, January 2020, and January 2021. Note: the data used in the Biologics Audit is a subset of this whole dataset.

The records submitted to us should not be presumed to represent the whole UK IBD population, estimated at greater than 500,000 people. We do not receive all records from all hospitals delivering IBD care in the UK, some patients receive their care wholly in primary care and, for the reasons alluded to above (section 9.2), there is a bias towards Crohn's disease in the records we receive.

	Cumulative to Jan 2019	Cumulative to Jan 2020	Cumulative to Jan 2021
Total number of IBD patients with a recorded diagnosis	48,401	59,471	71,022
Number of patients with Crohn's disease (CD)	23,449	29,293	34,780
Number of patients with ulcerative colitis (UC)	21,746	27,614	33,281
Number of patients with IBD Unclassified (IBDU)*	3,206	2,564	2,961

* Cumulative numbers have fallen as a result of refinements in data capture systems

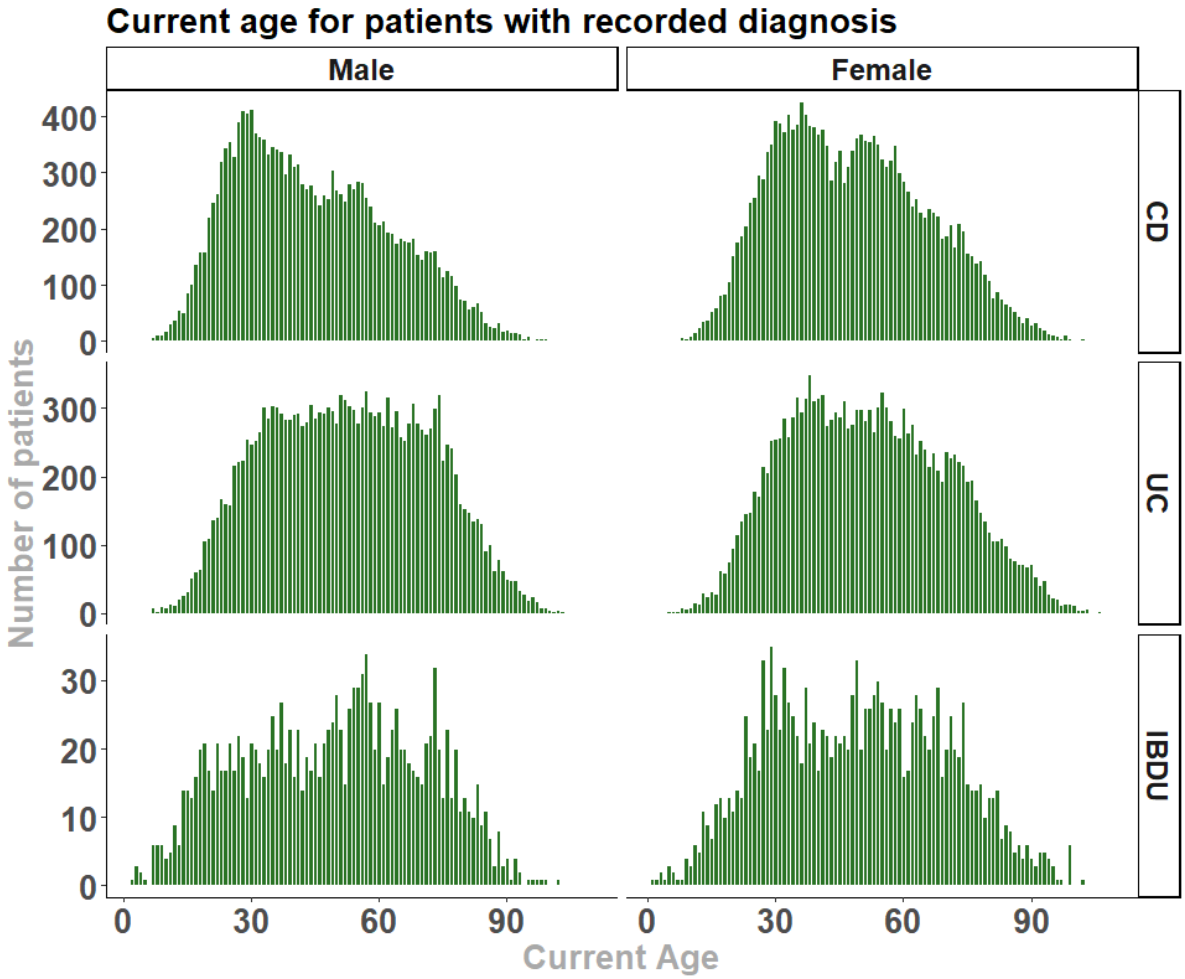
	Cumulative to Jan 2019 (%)	Cumulative to Jan 2020 (%)	Cumulative to Jan 2021 (%)
Crohn's disease gender proportion (M:F)	45 : 55	47 : 53	47 : 53
Ulcerative colitis gender proportion (M:F)	51 : 49	52 : 48	52 : 48
IBDU gender proportion (M:F)	44 : 56	48 : 52	49 : 51

[2] Freeman, K., Ryan, R., Parsons, N., *et al.* (2021). The incidence and prevalence of inflammatory bowel disease in UK primary care: a retrospective cohort study of the IQVIA Medical Research Database. *BMC Gastroenterology*, 21(1):139.

10.2 Age of patients

We collect both the age and sex of patients who participate in our Registry, to better understand how IBD relates to and is influenced by these key determinants.

The chart below shows the distribution of patients' ages held in the Registry, divided by disease and sex (data as at January 2021).

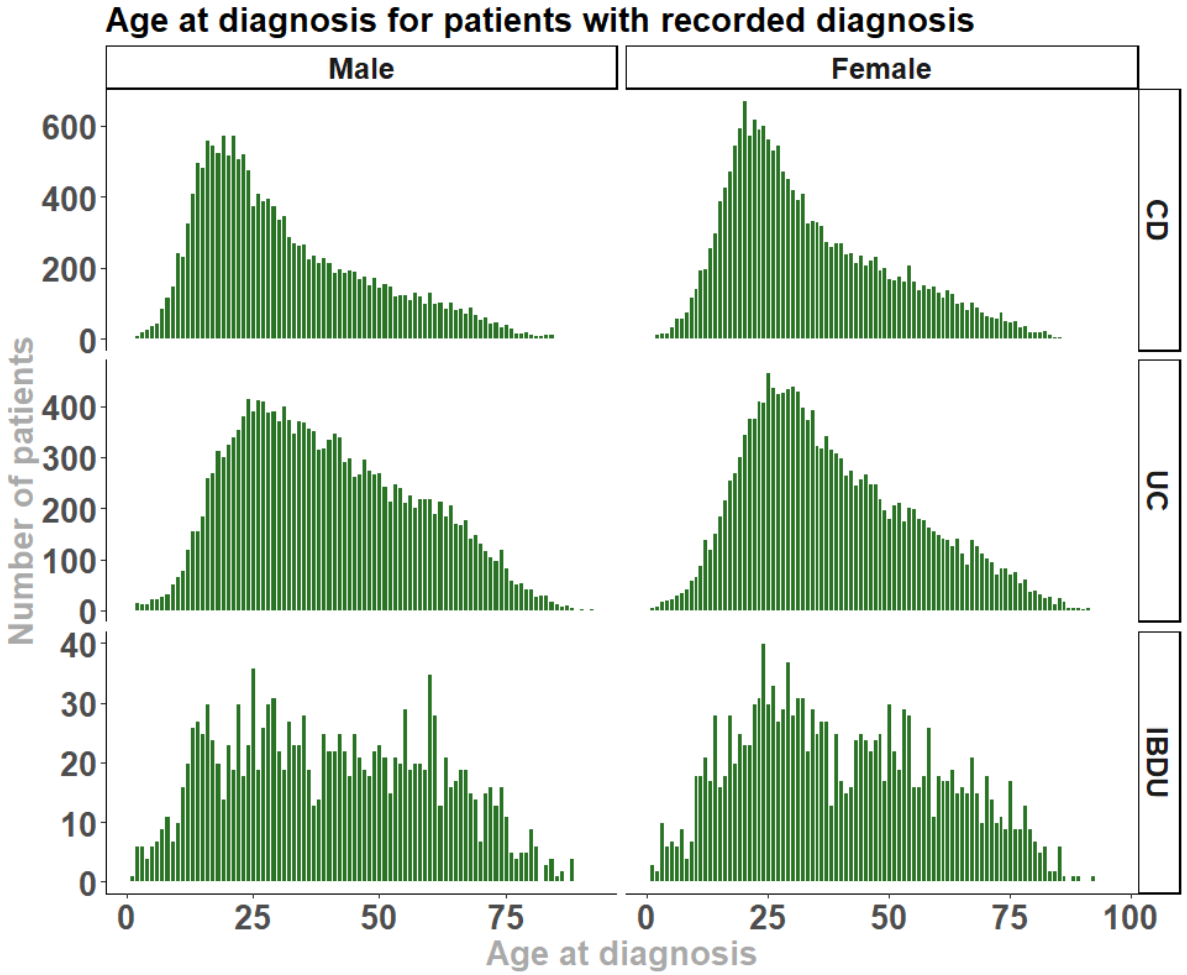


The analysis includes both adult and paediatric (children's) records. The three analyses are by Crohn's disease (CD), ulcerative colitis (UC) and IBDU (IBD Unspecified).

10.3 Age at diagnosis

We also calculate age at diagnosis of patients who participate in our IBD Registry to further support our understanding of how IBD impacts people.

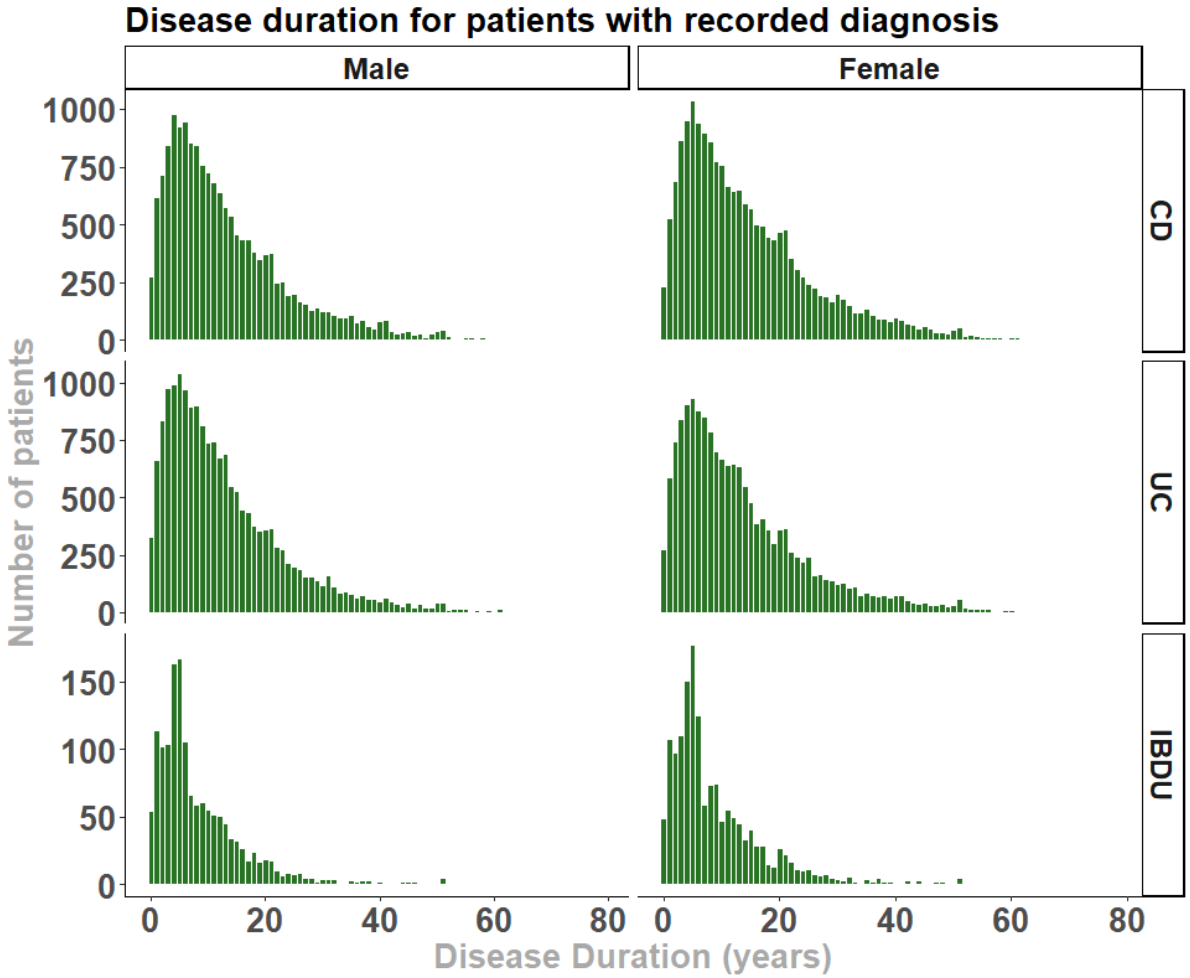
Age at diagnosis held in the Registry as at January 2021, displayed by disease and sex.



We look forward to further exploring this feature of IBD, not least to look for trends in age of onset over time and differences between types of IBD and between the sexes.

10.4 Disease Duration

Based on date of diagnosis, we continue to receive records of patients both from early in the course of their IBD and many years after being diagnosed.



11 Impact of COVID-19

We are grateful to the many IBD teams who continued to submit data to the UK IBD Registry during the months when COVID-19 was impacting heavily on healthcare delivery. The data we received showed an unsurprising change from face-to-face to virtual consultations and two significant changes in prescribing practice.

The change in consultations reflected effects of COVID-19 on access to outpatient services and perhaps patients' desires to avoid placing themselves at increased risk of contracting COVID-19.

In the light of uncertainties about increased risk from COVID-19 for patients taking drugs that modify a patient's immune system (immunomodulators such as azathioprine, and corticosteroids such as prednisolone), our data showed a marked drop in new prescriptions for azathioprine and 6-mercaptopurine and a shift away from prednisolone towards oral steroids acting more specifically on the intestine.

These changes were not unanticipated, but we were encouraged to see that analysis of data we were receiving detected these changes within three months of the first lockdown, indicating the effectiveness of our real-world data capture systems and the commitment of IBD teams to submit their data.

11.1 COVID-19 IBD Risk Tool

For our part, we built the COVID-19 IBD Risk Tool for patients to use for self-assessment. In this way we helped almost 41,000 people with IBD, as well as the clinical teams that support them.

The tool was built in record time – 8 days – using our existing patient survey tool and secure data platform, as well as our deep background in data security and information governance, ensuring that, whilst done quickly, it was still done well.

We are touched by the feedback and thanks we have received from patients, and proud that we have been able to do something bringing reassurance to so many, at a time of worrying uncertainty.

Now in 2021, we are pleased to return to our review of biologics in IBD.

12 Revising the focus of the national IBD audit

The IBD Registry have been working closely with the BSG IBD Section on revisiting and revising the Key Performance Indicators (KPIs) for clinical care in IBD.

Dr Nabil Quraishi, BSG IBD subcommittee Quality Improvement lead writes:

"The indicators that reflect the delivery of inflammatory bowel disease (IBD) care are being revised by the BSG IBD section, IBD Registry and Crohn's & Colitis UK, with the aim of continuing to improve and reduce the variability of the standards of health care and quality of service that patients with IBD receive.

With a growing population of IBD patients within the UK, access to newer therapies, evolution of treatment targets and a shift towards patient empowerment, there is now a need to revisit quality indicators. The recent national IBD benchmarking that combined feedback from patients and services through IBD UK highlighted key themes that urgently need addressing. These included impact of delayed diagnosis, rapid access to specialist care during flares and need for personalised care plans. Furthermore, the UK has seen the rapid introduction of major, and possibly long-lasting changes in provision of IBD services during the COVID-19 pandemic. With these changes likely to have a significant impact on clinical pathways and patient outcomes / experiences there is now a need to reassess which quality metrics can provide dynamic benchmarking of important contemporary challenges and help to facilitate positive change for patients and services.

Through several discussions with key stakeholders, the following four quality measures were proposed as having the potential to form key performance indices:

1. Time from primary care referral to diagnosis of IBD in secondary care

2. Time to initiation of IBD-specific treatment following a diagnosis of IBD

3. Excess steroid use

4. Biologic and immunomodulator pre-screening and assessment (existing KPIs)

These proposed KPIs are now going through a thorough evaluation (via a Delphi process supported by the IBD Registry) to understand their ability to assess performance and process, allow robust representation of the quality of care, support accountability and quality improvement. In addition, the success of these KPIs will also strongly lie in their adoption across services nationally. Our aim is to ensure there is minimalism and ease in data collection without compromising its representativeness and robustness in benchmarking quality of care.

We anticipate completion of the Delphi process by September 2021."

We are pleased to be able to work with and support the BSG IBD Section in this important process. The KPIs run by calendar year (Jan- Dec 2021), so the resulting move to the new KPIs is envisaged for start in 2022.

13 About the IBD Registry

13.1 Purpose, Structure and Governance

The purpose of the IBD Registry is to improve the health of people living with inflammatory bowel disease in the UK by the collection and analysis of data in order to improve understanding of the care of people with IBD and their treatments and to facilitate research.

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 and registered address as 3 St Andrews Place, Regent's Park, London NW1 4LB (*note*: this is not our main office -please see below for our address).

14 Citation and Correspondence

14.1 Acknowledgment and Citation

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

UK IBD Registry. Biological Therapies Annual Report (2021). London: UK IBD Registry Ltd, 2021.

14.2 Contact and Correspondence

Our website has further information on our work on quality improvement and in participation in the IBD Biological Therapies 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 biological therapies 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: Suite 9, Epsom Workhub, Epsom Square, 6-7 Derby Square, Epsom KT19 8AG