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Original research

Establishing key performance indicators for inflammatory bowel disease in the UK

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ABSTRACT

Background and aims Healthcare quality improvement (QI) is the systematic process to continuously improve the quality of care and outcomes for patients. The landmark Inflammatory Bowel Disease (IBD) UK National Audits provided a means to measure the variation in care, highlighting the need to define the standards of excellence in IBD care. Through a consensus approach, we aimed to establish key performance indicators (KPIs), providing reliable benchmarks for IBD care delivery in UK.

Methods KPIs that measure critical aspects of a patient journey within an IBD service were identified though stakeholder meetings. A two-stage Delphi consensus was then conducted. The first involved a multidisciplinary team of IBD clinicians and patients to refine definitions and methodology. The second stage assessed feasibility and utility of the proposed QI process by surveying gastroenterology services across UK.

Results First, the four proposed KPIs were refined and included time from primary care referral to diagnosis in secondary care, time to treatment recommendation following a diagnosis, appropriate use of steroids and advanced therapies prescreening and assessment. Second, the Delphi consensus reported >85% agreement on the feasibility of local adoption of the QI process and >75% agreement on the utility of benchmarking of the KPIs.

Conclusions Through a structured approach, we propose quantifiable KPIs for benchmarking to improve and reduce the individual variation in IBD care across the UK.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Several quality improvement (QI) initiatives in inflammatory bowel disease (IBD) nationally have previously led to improvement in patient care and service delivery.

WHAT THIS STUDY ADDS

⇒ There is now a clear need to reassess which quality metrics can now provide dynamic benchmarking of important contemporary challenges by means of a minimalistic but robust data collection methodology.

⇒ Through a two-stage Delphi consensus with key stakeholders and the IBD clinical/patient community, we have established four key performance indicators (KPIs) along with relevant methodology for implementation nationally.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This British Society of Gastroenterology IBD QI initiative will focus on the performance of IBD services against defined KPIs and will complement the IBD UK benchmarking tool which assess performance against defined IBD standards via patient surveys and service self-assessments.

INTRODUCTION

A number of national IBD (inflammatory bowel disease) quality improvement (QI) initiatives have been undertaken in the UK over the last 15 years.[1] The UK IBD Audit, established in 2004, undertook five rounds of national audit between 2005 and 2016.[2] This transitioned to the UK IBD Registry—a national registry that collects and reports patient level data

to assist IBD teams in providing better care to their patients. The IBD Registry facilitated longitudinal collection and reporting of metrics around screening prior to biologics initiation and monitoring.[3] In 2019, the British Society of Gastroenterology (BSG) guidelines and the IBD UK Standards defined the process and outcome measures that represent a high-quality clinical IBD service. Subsequently, the IBD UK patient survey and clinical service self-assessment in 2019/2020 allowed services and patients to feedback on care against the IBD Standards.[4] The national report that followed 'Crohn's and Colitis Care in the UK: The Hidden Cost and a Vision for Change' highlighted key areas that needed addressing, including delays in diagnosis, the need for quicker access to specialist advice and treatment and for more personalised and holistic care.[5] To date, no service in the UK currently meets all criteria set and there remains significant variation in care.[4 6 7] The ability to monitor and benchmark services can help stream pathways towards patient-centred healthcare, as well as guide teams towards meaningful QI targets. This process drives change towards improvements in clinical outcomes and IBD patient experience.[8 9] Key performance indicators (KPIs) are meaningful and manageable quality metrics that aim to measure performance to identify quality of service, allow benchmarking (to provide comparability) and facilitate recognition of areas for improvement.[10]

With a growing population of patients with IBD within the UK, access to newer advanced therapies, evolution of treatment targets, a shift towards patient empowerment and introduction of national programmes such as Getting It Right First Time, there is now a need to revisit quality indicators.[11] Furthermore, the UK has seen the rapid introduction of major, and possibly long-lasting adaptations in provision of IBD services during the COVID-19 pandemic.[12] There is now a clear need to reassess which quality metrics can provide dynamic benchmarking of important contemporary challenges that will help facilitate a positive change for patients and services.

Through key stakeholder meetings and Delphi consensus surveys, we aimed to define clinically relevant KPIs with a strong emphasis for patient care and deliverability for IBD services across the UK.

METHODOLOGY

Following stakeholder meetings with the BSG IBD section, IBD Registry, patient charity Crohn's and Colitis UK, BSG Clinical Services and Standards Committee and the Royal College of Physicians, four candidate KPIs were identified by informal consensus:

KPI 1—Time from primary care referral to diagnosis in secondary care.

KPI 2—Time to treatment recommendation following a diagnosis.

KPI 3—Appropriate use of steroids.

KPI 4—Advanced therapies prescreening and assessment.

As summarised in table 1, we undertook a two-stage Delphi consensus to further discuss the relevance and feasibility of the four identified KPIs along with proposed methodology for data collection, standards to assess against and benchmarking.[13] An initial proposal on the KPI definitions and the QI

Table 1 Summary of methodological approach for establishing key performance indicators (KPIs) in inflammatory bowel disease (IBD)

Initial stakeholder meeting to propose and develop KPIs	Four KPIs were proposed through meetings with key stake holders and a preliminary methodological approach for the QI process outlined: 1. Time from primary care referral to diagnosis in secondary care 2. Time to treatment recommendation following a diagnosis 3. Appropriate use of steroids 4. Advanced therapies prescreening and assessment
Delphi survey round 1	KPIs with methodology of the QI process presented to a clinical IBD expert panel and patients Statements across the following themes for each of the candidate KPIs presented to the panel for ranking using a 5-point Likert scale ('strongly agree', 'agree', 'neither agree nor disagree', 'disagree', 'strongly disagree' ► Is the KPI being measured is a relevant and critical part of a patient's experience? ► Does the methodological process appropriately represent that journey? ► What standards would be acceptable to help understand performance? ► Is the QI process achievable nationally? ► Is it an important clinical priority in the current era? ► Does engaging in this QI initiative have the potential to lead to a favourable change?
Round 1 report and stakeholder meeting	Report following round 1 generated for review. Stakeholder meetings to update the KPI and QI methodology based on feedback from round 1
Delphi survey round 2	KPIs with updated methodology of the QI process presented to the wider BSG membership Statements presented to survey opinions and challenges on local relevance (utility) and feasibility for participation in this QI programme using a 5-point Likert scale
Round 1 report and stakeholder meeting	Report following round 2 generated for review Stakeholder meetings to update the KPI and QI methodology based on feedback from round 2

BSG, British Society of Gastroenterology; QI, quality improvement.

process were developed and agreed on by stakeholder members prior to round 1 of Delphi consensus survey. In round 1, a proposed description of the data collection process, metrics and outcome was outlined along with statements across several domains supporting each candidate KPIs (as shown in online supplemental document 1). Panellists were asked to independently rank the statements for each KPI, using a 5-point Likert scale along with a free-text option.

KPI definitions and methodology were updated for the next round of the Delphi consensus survey (online supplemental document 2). Round 2 aimed to outline opinions and challenges on local relevance and feasibility for participation in this QI programme as well as clarifications on contentious aspects. A similar 5-point Likert scale was used. The wider BSG membership (not limited to the IBD section/practitioners) was then invited to take part in round 2. The Delphi surveys were conducted using Research Electronic Data Capture electronic data capture tools hosted by the IBD Registry team.[14 15]

RESULTS

Round 1 of Delphi consensus survey

Sixty participants completed the Delphi survey. A minimum number of patients or a fixed time period for data collection was no longer mandated. Data items being collection were reduced further and benchmarking against national median performance with percentile rank reporting was proposed for adoption for KPI 1 and 2 and defined national standards refined for KPI 3 and 4. A full demographic of panellists and overview of results for round 1 is shown in online supplemental document 1.

Round 2 of Delphi consensus survey

Round 2 of the survey was conducted between April 2022 and May 2022. A total of 72 complete responses across 53 NHS sites across UK; 44 based in England, 5 in Scotland and 4 in Wales. There were no respondents from hospitals based in Northern Ireland.

Of 58, 25 (43.1%) sites reported an estimated IBD population base of >4000 patients while 11/58 (22.34%) reported an IBD population base of <2000 patients. Of 71, 34 (47%) of the respondent sites were already enrolled with the IBD Registry for the biologics therapies audit. The complete results from round 2 are shown in online supplemental document 1.

There was greater than 85% agreement among survey participants on the feasibility of local delivery based on the proposed methodology for each individual KPIs. There was greater than 75% agreement on the utility to the IBD service of benchmarking for each individual KPIs. Of 71, 60 (84.4%) IBD services expressed a preference for either a minimalistic approach or use a simple web-based tool for data collection rather than using the IBD Registry's current more comprehensive tools. However, comparatively, a greater proportion of sites participating in IBD Registry's biologics audit using the existing tools were keen to continue using it for data collection. Thirty-six per cent of respondents were happy to submit patient identifiers in patients who have not explicitly consented to the IBD Registry (allowed under S251 regulation/approved exemption). Thirty-nine per cent of respondents did not agree while 25% were not sure.

Following round 2, there were further meetings with stakeholder to address any concerns and finalise the KPI definitions and QI methodology to take forward. The steroid use benchmark was revised and the panel instead opted to benchmark against national performance rather than predefined standards.

KEY PERFORMANCES INDICATORS

Following these rounds of consensus-building surveys and stakeholder meetings the definitions, outcome measures, data collection, benchmarking and reporting methodologies for each of the KPIs have progressed through several iterations. These final agreed versions are presented as below.

KPI 1: time from primary care referral to diagnosis in secondary care

Outcome measure and definitions

The time to diagnosis KPI will measure the local performance for time to a documented diagnosis of IBD in secondary care following a primary care referral. Time to diagnosis is defined as days between date of an appropriate referral from primary care for suspected IBD to a documented diagnosis of IBD in clinical records in secondary care. Documented diagnosis is defined as a formal documentation of a confirmed diagnosis of IBD in the patient's records. The diagnosis of IBD would be based on the clinician's judgement, supported by a combination of relevant investigation. A highly likely suspected diagnosis of IBD (such as ileitis or segmental colitis) that warrant treatment or monitoring will be included in this definition.

Proposed data collection methodology

Data will be collected prospectively from all newly diagnosed patients over a period of a year. This may be done at any time point in the patient's initial journey following a diagnosis, that is, first outpatient or inpatient clinical review when the diagnosis is confirmed or treatment commenced. The aim is to collect data on as many patients as feasible with no defined minimum number of patients. A minimum threshold may, however, be set to allow benchmarking following preliminary statistical analysis. IBD services that find prospective data collection challenging may consider collecting data retrospectively.

Data items required for each patient enrolled

- Date of referral on the referral letter from primary care.

- Date of formal documentation of a confirmed diagnosis of IBD in the clinical records.
- Diagnosed as an inpatient following a following acute (non-elective) hospital admission (yes/no).

Setting and reporting standards for benchmarking

Benchmarking of individual sites will be performed against the national median performance and performance defined as percentile/rank in relation to national median. At present, a national standard/target for time to diagnosis cannot be defined; however, an exploratory standard may be used for statistical analysis. The local percentile rank, local median time and national median time to treatment recommendation following a diagnosis will non-publicly reported to the individual IBD services. Diagnoses made following hospitalisation in patients with prior primary care referrals will be reported separately but not as part of the KPI. It is envisaged that the initial round/s of QI will help determine national medians to help set a target waiting time for future rounds.

KPI 2: time to treatment recommendation following a diagnosis

Outcome measure and definitions

The time to treatment recommendation following a diagnosis KPI measures the local performance for time to recommendation of treatment for IBD following a diagnosis. Treatment is defined as oral or rectal mesalazine, thiopurines, biological therapies, small molecule drugs oral or rectal steroids, IBD-specific surgery, disease-modifying nutritional therapies (such as exclusive enteral nutrition) and therapies pertaining to IBD specific clinical trials. An active documented decision to watch and wait for mild disease will be considered as 'treatment' (eg, in patients with mild terminal ileitis). Advice/guidance given around management of Crohn's including advice given on smoking cessation or dietary change is excluded from the definition. For treatments commenced in secondary care and recommendations made to primary care—the date when the documented treatment recommendation was made will be recorded. Patients declining treatment would be included with recording of date of treatment recommended. Date treatment was commenced will be collected as a non-mandatory data point. Treatment commenced as an inpatient following hospitalisation (including those diagnosed on that admission) will be reported as separately but not part of the overall KPI.

Proposed data collection methodology

This will be a prospective data collection of all newly diagnosed patients over a period of a year. Patients in KPI2 should be linked to KPI1 with congruency in date of formal documentation of a confirmed diagnosis. Data items for KPI1 and KPI2 may, therefore, be collected together. This may be done at any time point of the patient's initial journey following a diagnosis, that is, first outpatient or inpatient clinical review following commencement of treatment. The aim is to collect data on as many patients as feasible with no defined fixed number of patients. A minimum threshold may, however, be set to allow benchmarking. IBD services that find prospective data collection challenging may consider collecting data retrospectively.

Data items required for each patient enrolled

- Date of formal documentation of a confirmed diagnosis of IBD in the clinical records.
- Date treatment recommended.
- Date treatment commenced (non-mandatory data item).
- First treatment received following a diagnosis as an inpatient following an acute (non-elective) hospital admission (yes/no).

Setting and reporting standards for benchmarking

As with KPI1, benchmarking of individual sites will be performed against the national median performance and performance defined as percentile/rank in relation to national median. At present, a national standard/target for time to treatment following diagnosis cannot be defined; however, an exploratory standard may be used for statistical analysis. The local percentile rank, local median time and national median time to treatment recommendation following a diagnosis will non-publicly reported to the individual IBD services. Treatment recommendation following diagnosis as an inpatient will be reported as a sub-KPI. It is envisaged that the initial round/s of QI will help determine national medians to help set a target waiting time for future rounds.

KPI 3: oral steroid use

Outcome measure and definitions

The oral steroid KPI measures the proportion of patients exposed to ≥2 courses and proportion of patients exposed ≥3 courses of oral steroids in a year in an unselected cohort of patients with IBD. A course of corticosteroids will be defined as a minimum of at least 5 days of consecutive use. Steroids would include any class of oral corticosteroids including budesonide. Enemas and suppositories will be excluded. Steroid use should measure those obtained through secondary care and primary care prescriptions as well as home supplies. Steroid use would include any given indication rather than IBD alone (the two multicentre national audits found only 3% of steroid excess was from non-IBD indications). Steroid excess is defined the prescription of 2 or more steroid courses over 12 months or >3 months over a 12-month period by the BSG IBD and European Crohn's and Colitis Organisation (ECCO) guidelines. The currently envisaged denominator for this KPI includes steroids exposed and unexposed patients, but a secondary set of analyses with the denominator of only steroids exposed

patients will be undertaken to allow validation and confirmation of this approach

Proposed data collection methodology

A consecutive unselected cohort of patients with IBD (regardless of prior steroid exposure) attending outpatient clinics will be invited to take part. A snapshot of steroid use over the prior 12 months will be assessed as per the definitions of a steroid course and metrics proposed. IBD services will be encouraged to capture data from a diverse range of clinical setting (that include flare and routine appointments) in order to reduce the risk of a selection bias. Data will be collected via dedicated online tools. Patients enrolled may potentially be invited to participate in a linked prospective patient reported steroid use QI process through the IBD Registry. The aim is to capture as many patients as feasible with no defined fixed number of patients. A minimum threshold may, however, be set to allow representative benchmarking. The eventual aim is to move towards a consecutive prospective clinician reported or patient reported steroid exposure data for this KPI.

Data items required for each patient enrolled

- Total number of courses of steroids in the last 12 months (≥0).
- Total duration (in weeks) of steroid use in the last 12 months (≥0).

Setting and reporting standards for benchmarking

For the initial round of QI, no standards are set for what would be considered to be appropriate steroid use for benchmarking. Benchmarking of individual sites will be performed against the national average proportion of patients exposed to ≥2 courses steroid courses in 1 year, average proportion of patients exposed to ≥3 courses of oral steroids in 1 year and median total duration (in weeks) of steroid use over 12 months. Individual site performance will be defined as percentile/percentile rank in relation to national median with reporting of metrics for each of the defined benchmarks. Outcomes from the initial round/s of QI may be used to formally develop a national standard for future rounds.

KPI 4: advanced therapies prescreening and assessment

Outcome measure and definitions

The advanced therapies prescreening and assessment KPI measures the proportion of patients meeting standards for pretreatment screening prior to initiation of advanced therapies and assessment of efficacy and safety after induction of therapy and at 1 year. Advanced therapies include biologics and small molecules that are used for treatment of IBD. Thiopurines and methotrexate are excluded. Pretreatment screening for infections prior to commencement of biologics is defined as per BSG guidance and includes HBV, HCV and HIV (and may include VZV if no history of chickenpox, shingles or varicella vaccination) and tuberculosis screen. This may have been performed at any time point in patient's immunosuppression history. The interval prior to repeating these tests would be based on the clinical team's discretion. For Janus kinase inhibitors pretreatment screening should include lipid profiles. Assessment of efficacy and safety following induction can be any documented review of patients between week 8 and week 20 after commencement of advanced therapies. Assessment of efficacy and safety at 1 year can be any documented review of patients between month 10 to month 14 after commencement of advanced therapies (if the respective treatment is still ongoing). This in-person or remote review at both these time points may be conducted by any competent member of the IBD service. The review should consider both safety and clinical parameters (including a patient-reported outcome measure), and an objective assessment of disease activity.

Proposed data collection methodology

The process is similar to the current IBD Registry biologics audit; however, with fewer data collection metrics. Data may be collected by IBD services both prospectively and retrospectively (case note reviews) and should include patients having commenced advanced therapies from January 2021. Data will be entered following the commencement of each new advanced therapy for an individual patient. A patient may, therefore, have multiple entries following sequential changes to their advanced therapy. A mid-treatment switch to a biosimilar, dose optimisation or a change in the mode of administration of the same advanced therapy (such as intravenous to subcutaneous) would not restart a data collection episode for that patient. A minimum number of patients is not defined but a minimum threshold will be set for representative benchmarking.

Data items collected for each patient enrolled

- Was the patient screened for infections before starting on an advanced therapy (split by individual screening parameters)? (Yes/No)
- Was there a documented assessment of efficacy and safety between week 8 and week 20 after commencement of advanced therapy in patients with ongoing use? (Yes/No/No longer on the treatment)
- Was there a documented assessment of efficacy and safety between month 10 and month 14 after commencement of advanced therapy in patients with ongoing use? (Yes/No/No longer on the treatment)

Setting and reporting standards for benchmarking

The standard for minimum expected proportion of patient's being prescreened prior to initiation of advanced is set at 95%. The standard for minimum expected proportion of patient's being assessment following induction and at 1 year after commencement

of advanced therapies are both set at 90%. The advanced therapy screening and assessment KPI will be reported to individual sites as three separate sub-KPIs each covering different aspects:

1. Screened prior to advanced therapy use (further split by individual parameters).
2. Documented assessment following induction of advanced therapy.
3. Documented assessment at 1 year following commencement of advanced therapy.

Reports will be provided to individual sites on the proportion of patients that met screening and assessment criteria as well as performance against national average.

DISCUSSION

Quality indicators for the medical management of IBD have been explored by other groups outside UK—for example, by Crohn's and Colitis Foundation of America in 2013, Canadian quality initiative Promoting Access and Care through Centres of Excellence in 2019 and more recently the Spanish Working Group on Crohn's Disease and Ulcerative Colitis in 2022.[9 16 17] KPIs from these international initiatives cover very similar themes such as structured clinical pathways or processes for the diagnosis, monitoring and treatment of IBD and improved access to helplines. Furthermore, quality measures specifically based patient-centred outcomes for IBD (International Consortium for Health Outcomes Measurement (ICHOM) Standard Set for IBD) have also been developed for use.[18] The goal of this QI initiative is to establish KPIs for IBD that could enable IBD services to make a measurable difference to patients by improving the safety, effectiveness, quality and experience of care being delivered. Establishing KPIs in IBD does not just rely on its importance in measuring a critical and modifiable aspect of a patient's journey. An equally strong focus is needed when it comes to the feasibility and adoption of the proposed QI methodology that represented this journey. The Delphi consensus survey focused on these issues and consequently lead to refinement of KPI definitions and the proposed methodology with consensus agreement among the UK IBD community.

The importance of the four KPIs as a significant clinical priority was highlighted by both IBD services and patients in the Delphi consensus survey. Delay in diagnosis and treatment of IBD have significant short-term and long-term implications to the patient and the IBD service. The POP-IBD study reported that less than half of IBD patients with a delayed diagnosis received specialist review within 18 months following initial primary care presentation.[19] Delayed diagnosis has been shown to be associated with higher IBD-related complications including hospitalisation, emergency surgery, corticosteroid use and strictures.[20–22] A key finding demonstrated in the IBD UK National Report was that over a quarter of patients waited over a year for a diagnosis with 41% visiting A&E at least once prior to their diagnosis.[4] Furthermore, it is well recognised that both UC and Crohn's are progressive chronic diseases and an early treat to target approach is associated with favourable outcomes.[23 24] Streamlining secondary care pathways to facilitate early diagnosis and treatment would consequently lead to improved patient outcomes and quality of life measures.

The evidence on the detrimental impact of excessive steroid use on quality of life and long-term outcomes in IBD is clear and reduction of steroid use is universally advocated by IBD societies.[6 25 26] There was a strong consensus agreement on the appropriateness of the steroid use KPI especially considering it had been validated via the national multicentre audits.[27 28] These had identified avoidable or potentially avoidable steroid excess in 50% of patients who met the definition for steroid excess. This steroid KPI aims to facilitate evaluation of steroid use rather than steroid excess within individual IBD services. Repeated courses of steroids without institution of an appropriate maintenance regime are associated with poor care.[29] Understanding individual steroid use would allow IBD services to consider initiatives such as rapid access flare clinics, proactive disease control, patient empowerment and early institution and optimisation of maintenance therapies. The advanced therapies KPI is similar to the current IBD Registry's biologics therapies audit and QI programme and aims to measure the efficacy, safety and appropriate use of biological therapies.[3] The four KPIs represent an appropriate mixture of process and outcome measures to reflect the performance of IBD services.

The methodological approach proposed caters for under resourced sites with data items for each KPI kept to an absolute minimum without significantly compromising its integrity. This was particularly important for those services which continue to receive paper referrals from primary care or do not have robust and accessible electronic health records (eHRs). The survey suggested that IBD services currently not participating with the IBD Registry's biologics audit expressed a preference for a bespoke web-based data entry tool. While this is an appealing methodology for retrospective audit data collection, multiple and different fully integrated data collection systems are already in clinical use for the sites engaged with the IBD Registry that allow prospective data capture during routine care. It would be desirable that most IBD services will eventually transition to using these integrated IBD Registry data collection systems that facilitate rapid cycles of analysis and near-real time feedback. Consistently, there was a relatively strong consensus to move towards a rolling prospective QI methodology as this would facilitate an iterative process that will build on successes and goalposts identified. This need for continual reassessment is an important aspirational goal, but currently unrealistic especially in absence of integrated national eHRs similar to Joint Advisory Group endoscopy KPI reporting.[30 31] Nearly half of the

respondents felt the QI initiative will be representative of their IBD population, while the other half did not believe it would be or were not sure. The adequacy representation will need to be explored further in future with formal feedback from sites following in the initial round of the QI initiative.

The Delphi surveys highlighted several pitfalls in the QI strategy which consequently led to adaptation or clarification in definitions and methodology. It was clear that the proposed KPIs could potentially be influenced by factors outside the control and scope of the secondary care IBD team (eg, primary care referrals to 2-week wait colorectal clinics, patient-related factors and access to diagnostic imaging). Conversely, it is anticipated that identification of these factors would in fact allow streamlining of pathways direct to 'suspected IBD' clinics and establishment of local policies for rapid management of flares.

The process towards the development of formal consensus derived KPIs in IBD aspires to establish a clear shared understanding with IBD services nationally of what QI in critical aspects of a patient's journey could potentially achieve. Through these KPIs, IBD services will be able to make an inference about the quality of care provided and indicate areas that require more detailed investigation. Our next step is to now progress towards running this QI initiative as a pilot across a few IBD services nationally.

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REFERENCES

1 IBD Standards Group. Standards for the Healthcare of people who have inflammatory bowel disease, IBD standards. 2013. Available: www.ibdstandards.org.uk
2 IBD audit programme 2005–2017. *Review of events, impact and critical reflections*. Royal College of Physicians, 2018.
3 IBD Registry biological therapies audit statement of purpose, scope and requirements. n.d. Available: https://ibdregistry.org.uk/
4 Hawthorne AB, Glatter J, Blackwell J, *et al*. Inflammatory bowel disease patient-reported quality assessment should drive service improvement: a national survey of UK IBD units and patients. Aliment Pharmacol Ther 2022;56:625–45.
5 Crohn's and colitis care in the UK: The hidden cost and a vision for change. Available: https://s3.eu-west-2.amazonaws.com/files.ibduk.org/documents/CROJ8096-IBD-National-Report-WEB-210427-2.pdf [Accessed 7 Oct 2022].
6 Lamb CA, Kennedy NA, Raine T, *et al*. British Society of gastroenterology consensus guidelines on the management of inflammatory bowel disease in adults. *Gut* 2019;68:s1–106.
7 Kapasi R, Glatter J, Lamb CA, *et al*. Consensus standards of healthcare for adults and children with inflammatory bowel disease in the UK. Frontline Gastroenterol 2020;11:178–87.
8 Louis E, Dotan I, Ghosh S, *et al*. Optimising the inflammatory bowel disease unit to improve quality of care: expert recommendations: table 1. *ECCOJC* 2015;9:685–91.
9 Melmed GY, Siegel CA, Spiegel BM, *et al*. Quality indicators for inflammatory bowel disease: development of process and outcome measures. Inflamm Bowel Dis 2013;19:662–8.

10 Health Information and Quality Authority (HIQA). *Guidance on developing key performance indicators and minimum data sets to monitor healthcare quality*. Dublin: HIQA, 2013.
11 GIRFT national report on Gastroenterology. Available: https://future.nhs.uk/GIRFTNational/view?objectId=112161125 [Accessed 7 Oct 2022].
12 Kennedy NA, Hansen R, Younge L, *et al*. Organisational changes and challenges for inflammatory bowel disease services in the UK during the COVID-19 pandemic. Frontline Gastroenterol 2020;11:343–50.
13 Brown BB. Delphi process: A methodology used for the Elicitation of opinions of experts. 1968.
14 Harris PA, Taylor R, Thielke R, *et al*. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009;42:377–81.
15 Harris PA, Taylor R, Minor BL, *et al*. The REDCap Consortium: building an international community of software platform partners. J Biomed Inform 2019;95:103208.
16 Bitton A, Vutcovici M, Lytvyak E, *et al*. Selection of quality indicators in IBD: integrating physician and patient perspectives. *Inflamm Bowel Dis* 2019;25:403–9.
17 Calvet X, Panés J, Gallardo-Escudero J, *et al*. Multicriteria decision analysis for updating of quality indicators for inflammatory bowel disease comprehensive care units in Spain. *J Crohns Colitis* 2022;16:1663–75.
18 Kim AH, Roberts C, Feagan BG, *et al*. Developing a standard set of patient-centred outcomes for inflammatory bowel Disease-an international, Cross-disciplinary consensus. J Crohns Colitis 2018;12:408–18.
19 Blackwell J, Saxena S, Jayasooriya N, *et al*. Prevalence and duration of gastrointestinal symptoms before diagnosis of inflammatory bowel disease and predictors of timely specialist review: a population-based study. J Crohns Colitis 2020. doi:10.1093/ecco-jcc/jjaa146. [Epub ahead of print: 15 Jul 2020].
20 Walker GJ, Lin S, Chanchlani N, *et al*. Quality improvement project identifies factors associated with delay in IBD diagnosis. Aliment Pharmacol Ther 2020;52:471–80.
21 Ricciuto A, Mack DR, Huynh HQ, *et al*. Diagnostic delay is associated with complicated disease and growth impairment in Paediatric Crohn's disease. *J Crohns Colitis* 2021;15:419–31.
22 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;57:635–52.
23 Turner D, Ricciuto A, Lewis A, *et al*. STRIDE-II: An update on the selecting therapeutic targets in inflammatory bowel disease (STRIDE): Initiative of the International Organization for the study of IBD (IOIBD): Determining therapeutic goals for treat-to-target strategies in IBD. *Gastroenterology* 2021;160:S0016-5085(20)35572-4:1570–83.:.
24 Plevris N, Fulforth J, Lyons M, *et al*. Normalization of fecal calprotectin within 12 months of diagnosis is associated with reduced risk of disease progression in patients with Crohn's disease. Clin Gastroenterol Hepatol 2021;19:1835–44.
25 Ford AC, Bernstein CN, Khan KJ, *et al*. Glucocorticosteroid therapy in inflammatory bowel disease: systematic review and meta-analysis. *Am J Gastroenterol* 2011;106:590–9.
26 Gomollón F, Dignass A, Annese V, *et al*. 3rd European Evidence-based Consensus on the Diagnosis and Management of Crohn's Disease 2016: Part 1: Diagnosis and Medical Management. *ECCOJC* 2017;11:3–25.
27 Selinger CP, Parkes GC, Bassi A, *et al*. A multi-centre audit of excess steroid use in 1176 patients with inflammatory bowel disease. *Aliment Pharmacol Ther* 2017;46:964–73.
28 Selinger CP, Parkes GC, Bassi A, *et al*. Assessment of steroid use as a key performance indicator in inflammatory bowel disease-analysis of data from 2385 UK patients. Aliment Pharmacol Ther 2019;50:1009–18.
29 Targownik LE, Nugent Z, Singh H, *et al*. Prevalence of and outcomes associated with corticosteroid prescription in inflammatory bowel disease. Inflamm Bowel Dis 2014;20:622–30.
30 Rees CJ, Koo S, Anderson J, *et al*. British Society of gastroenterology endoscopy quality improvement programme (EQIP): overview and progress. Frontline Gastroenterol 2019;10:148–53.
31 Standards. Joint advisory group of GI Endoscopy. Available: https://www.thejag.org.uk/the-standards [Accessed 2 Oct 2022].

Supplementary Document 1

Delphi survey invitation for Round 1

Establishing Key Performance Indicators for Diagnosis and Management of Inflammatory Bowel Disease in UK – KPI development Summary

Introduction

The delivery of inflammatory bowel disease (IBD) care is being reviewed in order to improve and reduce the variability of the standards of health care and quality of service that patients with IBD receive (1-3). The ability to monitor and benchmark services can help stream pathways towards patient-centred health care, as well as guide and focus clinical service commissioning towards greater efficiency. This process would ultimately drive change that leads to improvements in clinical outcomes and experiences of patients with IBD. Key performance indicator (KPIs) are quality metrics that aim to measure performance to identify quality of service, allow benchmarking (to provide comparability) and facilitate recognition of areas for improvement of the service being delivered (4). These KPIs should be able to assess performance and process, allow robust representation of the quality of care, support accountability and quality improvement. Monitoring and benchmarking KPIs to individual IBD services can help drive trusts towards targeted quality improvements at a local level.

Several quality and performance indicators have been developed and implemented to cover a range of areas of IBD practice in the UK over the last 15 years (5). The IBD Audit, established in 2004, undertook 5 rounds of national audit between 2005 to 2016 on a nearly biannual basis (6). This captured data on inpatient care, experiences, primary care services, organisational care and biological therapies and led to improvements that included a reduction in adult inpatient IBD mortality and time from diagnosis to commencement of treatment with biological therapies. This then transitioned to the IBD Registry which facilitated longitudinal collection and reporting of metrics around screening prior to biologics initiation and monitoring of biological therapies (7). 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 (2, 8). The recent national IBD benchmarking that combined feedback from patients and services through IBD UK highlighted key themes that urgently need addressing (9). 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 (10). With these changes likely to have a significant impact on clinical pathways and patient outcomes / experiences there is now a

clear need to reassess which quality metrics can now provide dynamic benchmarking of important contemporary challenges that will help facilitate a positive change for patients and services.

The identification of KPIs for IBD services will provide consensus-derived standards, thereby delivering a tool for monitoring quality throughout providers of such services in the UK. Through panel meetings with Stakeholders including the BSG IBD Section, IBD Registry, CCUK and IBD UK (and RCP) four potential KPIs have been identified for further exploration.

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**

The primary aim of this Delphi process is to obtain expert consensus on KPIs and the associated quality improvement / benchmarking process with respect to its relevance, feasibility for IBD services and patients across the UK.

Quraishi MN, *et al. Frontline Gastroenterol* 2023;0:1–8. doi: 10.1136/flgastro-2023-102409

Methodology

A two stage Delphi consensus-building approach will be carried out. Panellists will be selected from key stakeholder groups including BSG IBD Section, IBD Registry, IBD UK, CCUK and regional IBD service representatives (including nurses, trainees and across different District General Hospitals and Teaching Hospitals). The Delphi survey will be conducted using REDCap. In Round 1, a proposed description of the data collection process, metrics and outcome will be outlined along with statements across several domains supporting each candidate KPIs (as shown in the following sections). Panellists will be asked to independently rank the statements for each KPI, using a 5-point Likert scale ('strongly agree', 'agree', 'neither agree nor disagree', 'disagree', 'strongly disagree'). For each statement, panellists will be given the option to select 'unable to comment' as an alternative response. Panellists will also be given the option to provide free-text comments to support and elaborate on their decision.

Responses to the Round 1 survey will be analysed by the representative members of BSG IBD Subcommittee, IBD Registry and CCUK. For a statement to be accepted, at least 80% consensus (agree or strongly agree) will be needed. The relevance/importance of the candidate KPI will initially be assessed based on consensus at which point it may be rejected or accepted as a KPI. For KPIs that are accepted, revisions will then be made to the proposed data collection process, clinical and patient reported metrics being collected and reporting of the benchmarking process based on the responses. The revised survey will then be subject to Round 2 of the Delphi process with a potential for Round 3 depending on the degree of consensus obtained.

Quraishi MN, *et al. Frontline Gastroenterol* 2023;0:1–8. doi: 10.1136/flgastro-2023-102409

KPI 1 and KPI 2: Time to diagnosis and time to treatment

Brief Summary

Delay in diagnosis and treatment of IBD have significant short and long-term implications to the patient suffering from the disease and the health service. These can have a major impact on the quality of life of patients, impede career aspirations and are associated with worse clinical outcomes (11-13). Furthermore, with rapidly rising incidence of IBD globally and point prevalence of IBD expected to hit 1% by 2028 in parts of UK, timely diagnosis is now a relevant public health priority (14). A recent study from the UK highlighted that patients waited over 5 years for a diagnosis from the onset of symptoms (15). Amongst patients later diagnosed with IBD, less than half received specialist review within 18 months from presenting with chronic GI symptoms. A key finding demonstrated in the IBD UK National Report (to be published) was that over a quarter of patients waited over a year for a diagnosis with 41% visiting A&E at least once prior to their diagnosis (9). Reaching a diagnosis of IBD consists of several discrete stages. With the broad variety of types and intensity of presenting symptoms this initial step involves referral from primary to secondary care. With the increasing uptake of non-invasive tests including faecal calprotectin in primary care this has helped with overcoming this to an extent. A further potentially modifiable cause of diagnostic delay is lack of access to rapid secondary care diagnostic pathways. The National Institute for Health and Care Excellence (NICE) quality standards for IBD states that patients with suspected inflammatory bowel disease should have a specialist assessment within 4 weeks of referral (16). However, as demonstrated through the IBD UK National Report, only 29% of patients surveyed had been seen by a specialist within 4 weeks. Furthermore, 24% of patients surveyed reported waiting two weeks or longer to start treatment after diagnosis. Understanding the pathways involved at different stage could inform effective interventions to reduce overall diagnostic and treatment delays.

Aim

Establish potential for time to diagnosis of IBD following referral to secondary care and time to commence IBD specific treatment following diagnosis as KPIs for assessing of quality of IBD care in UK

KPI 1: Time from primary care referral to diagnosis in secondary care

Definition: Time to diagnosis is defined as weeks between referral from primary care to a documented diagnosis of IBD in secondary care.

- Referral to secondary care is made through multiple referral pathways and may include referrals via choose and book, two week wait or straight to test.
- Documented diagnosis is defined as a formal documentation of a confirmed diagnosis of IBD in the patients records.
- Whilst an investigation may suggest or confirm a diagnosis of IBD, when and how this diagnosis is confirmed and document would be based on the discretion of the clinician rather than an investigation.

Proposed process for quality improvement analysis

- IBD services will be invited to collect defined metrics as part of the KPI.
- Data may be collected prospectively at the point of diagnosis or retrospectively at a later review.
- To facilitate comparability and benchmarking only patients with a new documented diagnosis of IBD made from a specified future date should be registered (date to be confirmed).
- A minimum of 25 newly diagnosed patients will be required to be registered per site for representative benchmarking. In order to avoid bias patients should not be pre-selected.
- A defined period of data collection is not needed as this will be a rolling QI metric with near-real time KPI reporting (once minimum dataset collected) .
- Diagnosis of IBD made during hospitalisation may need to be excluded from this KPI (Delphi). Whilst this is an important cohort of patients, it would be challenging to identify those out who have had an admission due to an acute onset of severe disease as opposed to those who may have had a significant diagnostic delay following referral from primary care. Measuring delays in elective care diagnostic activity may help provide a representation of organisational factors that lead to diagnosis delays resulting in hospitalisation.

Expected standard: Benchmark diagnostic times for each IBD service in relation to national performance of IBD services.

At present there is no defined nationally expected standard for time from referral to diagnosis in secondary care. Although the NICE IBD Quality standard [QS81] states patients must be seen in secondary care within 4 weeks of referral from primary care, this does not specify that diagnosis should have been made at this initial point of contact in secondary care. There is also no published national data on what the current interval referral to diagnosis interval is as well as what interval would be defined as a diagnostic delay.

Quraishi MN, *et al. Frontline Gastroenterol* 2023;0:1–8. doi: 10.1136/flgastro-2023-102409

In view of this we propose that the first round of national quality improvement analysis should benchmark diagnostic times for each IBD service against national performance of IBD services. This initial exercise may also help define expected targets that would need to be achieved as part of future rounds of audits.

Proposed metrics to measure KPI:

- Date of referral to secondary care (DD/MM/YYY)
- Date of a diagnosis (DD/MM/YYY)

Reported benchmarking outcome measures:

- Median weeks between referral from primary care to a documented diagnosis of IBD made by the IBD service being audited
- Percentile score/rank of the IBD service compared national performance metrics for KPI

KPI 2: Time to initiation of treatment following a diagnosis

Definition: Time to treatment is defined as weeks between a documented diagnosis of IBD in secondary care to commencement of disease modifying medical or surgical treatment.

- Documented diagnosis is defined as a formal documentation of a confirmed diagnosis of IBD in the patient's records
- Treatment is defined as oral or rectal mesalazine, thiopurines, biological therapies, small molecule drugs, steroids, IBD specific surgery, nutritional therapies and therapies pertaining to IBD specific clinical trials.

Proposed process for audit

- IBD services will be invited to collect defined metrics as part of the KPI.
- Data may be collected prospectively at the point of first initiation of treatment or retrospectively at a later review.
- To facilitate comparability and benchmarking only patients with a new documented diagnosis of IBD made from a specified future date should be registered (date to be confirmed).
- A minimum of 25 newly diagnosed patients will be required to be registered per site for representative benchmarking. In order to avoid bias patients should not be pre-selected.
- A defined period of data collection is not needed as this will be a rolling QI metric with near-real time KPI reporting (once minimum dataset collected) .
- First treatment of IBD started during hospitalisation can be included in this KPI. However, a documented diagnosis of IBD should not have been made on that admission unless a prior referral to secondary care had been received for secondary care elective service.

Expected standard: Benchmark time to treatment for each IBD service in relation to national performance of IBD services.

IBD-UK standards define time to treatment from diagnosis as 48 hrs moderate to severe and within 2 weeks for mild to moderate IBD. There were based on surveys done nationally of IBD units and patients along with expert consensus agreement. Using these standards is an option for benchmarking. However, there is a paucity of published national data on what the current time from diagnosis to treatment of IBD interval is as well as what interval would be defined as an expected treatment standard based on clinical and patient centred outcomes. Furthermore, there would be a need to minimum proposed standards that would take in to account patients who do not

necessarily need to start treatment immediately for IBD (for example patients with asymptomatic isolated mild terminal ileal disease).

In view of this we propose that the first round of national audit should benchmark time to treatment intervals for each IBD service against national performance of IBD services. This initial exercise may also help define expected targets that would need to be achieved as part of future rounds of audits.

Proposed metrics to measure KPI:

- Date of a diagnosis (DD/MM/YYY)
- Date of commencement of IBD specific treatment (DD/MM/YYY)

Reported benchmarking outcome measures:

- Median weeks between a documented diagnosis of IBD to commencement of IBD specific treatment by the IBD service being audited
- Percentile score/rank of the IBD service compared national performance metrics for KPI

KPI 3: Excess steroid use

Brief summary

Corticosteroids are the mainstay of treatment for rapid induction of remission in patient with active IBD. Its use is however limited in view of its inability to maintain remission and significant side effect profile (17). The BSG IBD and ECCO guidelines define steroid excess as two or more courses of corticosteroids in a 12 month period (2, 18). Steroid dependency is defined as an inability to wean below 10mg of prednisolone or 3mg of budesonide within 3 months of starting, or disease flare within 3 months of stopping steroids. A multicentre patient reported UK audit found that 14.8% of IBD patients had steroid dependency or excess in the UK (19, 20). Potentially half of these cases were avoidable with a number of service and patient level factors independently correlating with risks of excess steroid exposure. Following quality improvement interventions, that included patient and physician education and rapid access flare clinics, there was a significant reduction in risk of steroid dependency and excess for patients with CD and UC. Importantly the group demonstrated that an online assessment tool could easily and robustly be used to measure steroid excess in clinical practice. Collectively there is a strong case for excess steroid use as a KPI and will enable benchmarking of service based on clinical outcomes and provide targets for improvements.

Aim

Monitor and benchmark excess steroid use and steroid dependency in patients with IBD

Definition: Steroid excess is defined as the prescription of 2 or more course of steroids over a 12 month period or use of steroids for greater than 3 months over a 12-month period.

- Steroids would include any class of oral corticosteroids given for any indication.
- A course of corticosteroids is defined as a minimum of at least 7 days of consecutive use

Proposed process for audit

- IBD services will be invited to collect defined metrics as part of the KPI.
- Data may be collected by IBD services from patients as a retrospective snapshot of the prior 12 months their steroid history. This would be repeated every other year.
- Steroid use will include those obtained through secondary care and primary care prescriptions as well as home supplies.

- A minimum of 50 patients being prescribed steroids will be required per site for representative benchmarking.

Expected standard: Proportion of patient's prescribed steroids with steroid excess not exceeding 50%.

The two multicentre UK audits exploring steroid excess has consistently identified that 50% of patients with IBD had avoidable or potentially avoidable steroid excess. With the audit recruiting patients from geographically and clinically diverse centres in England, Wales and Scotland with a mix of district general and teaching hospitals, we expected this standard to be generalisable for IBD centres across UK. Furthermore, as steroid prescriptions for non-IBD indications were found in less than 3%, for ease of reporting, this KPI measurement would include steroid use for all indications.

Proposed metrics to measure KPI:

- Total number of courses of steroids in the last 12 months
- Total duration of steroid use in the last 12 months (weeks)

Reported benchmarking outcome measures:

- Proportion of patients with excess steroid use (numerator: total number of patients with excess steroid use; denominator: total number of patients prescribed steroids).
- Percentile score/rank of the IBD service compared to national performance metrics for KPI

KPI 4: Biologic and immunomodulator pre-screening and assessment

The biological therapies KPI is part of the ongoing IBD Registry's audit and quality improvement programme. (7) This initially originated in the RCP IBD program prior to its transition to the Registry in 2016 – 2017. These KPIs monitored three points during a patient's biologics treatment - initiation on biological therapy (pre-treatment checks), post induction review and a 12-month review. This KPI was chosen by the RCP's Transition Steering Group to focus on the findings and recommendations in the IBD biological therapies audit report published in 2016 with the aim to measure the efficacy, safety and appropriate use of biological therapies. IBD services participating in submitted to the registry received quarterly report benchmarking performance to national data, including subgroups based on demographics, disease phenotype, consent levels and biologics usage. Since start of data collection in May 2015, 74 sites have participated. Work is ongoing in understanding outcomes of the benchmarking process around quality improvement by participating clinical teams.

With the licensing of newer biological therapies (and small molecules) for the treatment of IBD, the biologics pre-screening and response monitoring is likely to be an effective metric for facilitating safe and effective use of these drugs (2). The potential of regular reporting of individual service benchmarking with patient outcomes will help drive a reform in pathways that facilitate recognition of primary non-response and need for early optimisation of biological therapies.

Aim

Benchmark proportion of patients screened prior to initiation and monitoring during the course of treatment with biological therapies at induction.

Definition: Proportion of patients meeting standards for pre-screening prior to initiation of biologics and immunomodulators and assessment of efficacy and safety after induction of therapy and at one year.

- Biological therapies and immunomodulators include any monoclonal antibodies used for treatment of IBD and for the purposes of the KPI includes small molecule drugs. Thiopurines and methotrexate will not be included within this definition.
- Pre-screening for infections prior to commencement of biologics is defined in both BSG and ECCO guidance and includes HBV, HCV and HIV (and may include VZV if no history of chickenpox, shingles or varicella vaccination and TB). This may have been performed at any timepoint in

patient's recent history. The interval prior to repeating these tests would be based on the clinical team's discretion.

- Assessment of efficacy and safety following induction can be any documented review of patients between week 8 to week 20 after commencement of biological therapies. This review should consider both safety and clinical and objective assessment of disease activity and will only include patients who are on ongoing treatment with that biologic at that timepoint.
- Assessment of efficacy and safety at one year can be any documented review of patients between month 10 to month 14 after commencement of biological therapies. This review should consider both safety and clinical and objective assessment of disease activity and will only include patients who are on ongoing treatment with that biologic at that timepoint.

Proposed process for audit

- IBD services will be invited to collect defined metrics as part of the KPI.
- Data may be collected by IBD services both prospectively and retrospectively (case note reviews) and should include patients having commenced biological therapies from Jan 2021
- Each of the proposed biologics KPIs will be collected as a 'Yes' or 'No' response.
- A minimum of 25 patients will be required per site for representative benchmarking and will be part of the same process of the Biologics Audit currently being delivered by the IBD Registry.

Proposed expected standard:

- **The standard for minimum expected proportion of patient's being pre-screened prior to initiation of biologics is set at 95%.**
- **The standard for minimum expected proportion of patient's being assessment following induction is set at 90%.**
- **The standard for minimum expected proportion of patient's being assessment at one year after commencement of biological therapies is set at 90%.**

At present there is no defined nationally expected standard for biologics pre-screening and monitoring. However, both BSG and ECCO guidelines make strong recommendations towards this. We therefore propose a minimum expected standard for these KPIs which would help continue to ensure there are robust protocols and pathways locally for safe effective use of these therapies.

Proposed metrics to measure KPI:

- Was the patient screened for infections before starting on a biological therapy?
- Was there a documented assessment of efficacy and safety between week 8 and week 16 after commencement of biologics in patients with ongoing use?
- Was there a documented assessment of efficacy and safety between month 10 and month 14 after commencement of biologics in patients with ongoing use?

Reported benchmarking outcome measures:

- Proportion of patients pre-screened prior to biologics use
- Proportion of patients with a documented assessment following induction of biological therapy
- Proportion of patients with a documented assessment at one year following commencement of biological therapy
- Percentile score/rank of the IBD service compared national performance for each of the biologics KPI

References

1. Kapasi R, Glatter J, Lamb CA, Acheson AG, Andrews C, Arnott ID, et al. Consensus standards of healthcare for adults and children with inflammatory bowel disease in the UK. Frontline Gastroenterol. 2020;11(3):178-87.

2. Lamb CA, Kennedy NA, Raine T, Hendy PA, Smith PJ, Limdi JK, et al. British Society of Gastroenterology consensus guidelines on the management of inflammatory bowel disease in adults. Gut. 2019;68(Suppl 3):s1-s106.

3. Louis E, Dotan I, Ghosh S, Mlynarsky L, Reenaers C, Schreiber S. Optimising the Inflammatory Bowel Disease Unit to Improve Quality of Care: Expert Recommendations. J Crohns Colitis. 2015;9(8):685-91.

4. Melmed GY, Siegel CA, Spiegel BM, Allen JI, Cima R, Colombel JF, et al. Quality indicators for inflammatory bowel disease: development of process and outcome measures. Inflamm Bowel Dis. 2013;19(3):662-8.

5. IBD Standards Group. Standards for the healthcare of people who have inflammatory bowel disease, IBD standards, 2013 update. Available online at www.ibdstandards.org.uk

6. IBD audit programme 2005–2017. Review of events, impact and critical reflections. Royal College of Physicians 2018.

7. IBD Registry Biological Therapies Audit Statement of Purpose, Scope and Requirements. Available online https://ibdregistry.org.uk/.

8. Kaplan GG, Windsor JW. The four epidemiological stages in the global evolution of inflammatory bowel disease. Nat Rev Gastroenterol Hepatol. 2020.

9. IBD UK National Report (To be published) - https://ibduk.org/.

10. Kennedy NA, Hansen R, Younge L, Mawdsley J, Beattie RM, Din S, et al. Organisational changes and challenges for inflammatory bowel disease services in the UK during the COVID-19 pandemic. Frontline Gastroenterol. 2020;11(5):343-50.

11. Lee DW, Koo JS, Choe JW, Suh SJ, Kim SY, Hyun JJ, et al. Diagnostic delay in inflammatory bowel disease increases the risk of intestinal surgery. World J Gastroenterol. 2017;23(35):6474-81.

12. Zaharie R, Tantau A, Zaharie F, Tantau M, Gheorghe L, Gheorghe C, et al. Diagnostic Delay in Romanian Patients with Inflammatory Bowel Disease: Risk Factors and Impact on the Disease Course and Need for Surgery. J Crohns Colitis. 2016;10(3):306-14.

13. Kang HS, Koo JS, Lee KM, Kim DB, Lee JM, Kim YJ, et al. Two-year delay in ulcerative colitis diagnosis is associated with anti-tumor necrosis factor alpha use. World J Gastroenterol. 2019;25(8):989-1001.

14. Jones GR, Lyons M, Plevris N, Jenkinson PW, Bisset C, Burgess C, et al. IBD prevalence in Lothian, Scotland, derived by capture-recapture methodology. Gut. 2019;68(11):1953-60.

15. Blackwell J, Saxena S, Jayasooriya N, Bottle A, Petersen I, Hotopf M, et al. Prevalence and duration of gastrointestinal symptoms before diagnosis of Inflammatory Bowel Disease and predictors of timely specialist review: a population-based study. J Crohns Colitis. 2020.

16. Inflammatory bowel disease Quality standard [QS81]. National Institute for Health and Care Excellence. .

17. Ford AC, Bernstein CN, Khan KJ, Abreu MT, Marshall JK, Talley NJ, et al. Glucocorticosteroid therapy in inflammatory bowel disease: systematic review and meta-analysis. Am J Gastroenterol. 2011;106(4):590-9; quiz 600.

18. Gomollon F, Dignass A, Annese V, Tilg H, Van Assche G, Lindsay JO, et al. 3rd European Evidence-based Consensus on the Diagnosis and Management of Crohn's Disease 2016: Part 1: Diagnosis and Medical Management. J Crohns Colitis. 2017;11(1):3-25.

19. Selinger CP, Parkes GC, Bassi A, Limdi JK, Ludlow H, Patel P, et al. Assessment of steroid use as a key performance indicator in inflammatory bowel disease-analysis of data from 2385 UK patients. Aliment Pharmacol Ther. 2019;50(9):1009-18.

20. Selinger CP, Parkes GC, Bassi A, Fogden E, Hayee B, Limdi JK, et al. A multi-centre audit of excess steroid use in 1176 patients with inflammatory bowel disease. Aliment Pharmacol Ther. 2017;46(10):964-73.

Demographics of panellists participating in Round 1 of Delphi consensus survey

A total of 106 individuals were invited of whom 60 completed the Delphi survey. The nature of Stakeholder representative panel selection meant that nearly all the clinical respondents were based in teaching hospitals or large district general hospitals. The responses requested were meant to be generic and based on national feasibility (as opposed to local feasibility). A breakdown of description / affiliation of the respondents is as shown in Table 1:

Table 1 – Delphi panellists	Count of Speciality
IBD Clinical Nurse Specialists	**2**
Barts Health NHS Trust	1
Nottingham University Hospitals NHS Trust	1
Gastroenterologists	**38**
Aintree University Hospital	1
Barts Health NHS Trust	2
Cambridge University Hospitals	2
County Durham and Darlington NHS Foundation Trust	1
Glasgow Royal Infirmary	1
Guy's & St Thomas	1
Hull University Teaching Hospitals	1
Leeds Teaching Hospitals NHS Trust	1
Newcastle Hospitals NHS Foundation Trust	4
Queen Elizabeth University Hospital, Glasgow	1
Royal Devon and Exeter NHS Foundation Trust	1
Royal Liverpool Hospital	1
Royal Liverpool University Hospital	1
Salford Royal NHS Foundation Trust	1
Sheffield Teaching Hospitals NHS Foundation Trust	1
Shrewsbury and Telford NHS Foundation Trust	1
South Tyneside And Sunderland NHS Foundation Trust	1
St Mark's Hospital	1
Stockport NHS Foundation Trust	1
The Pennine Acute Hospitals NHS Trust	1
The Royal Wolverhampton NHS Trust	2
The Royal Bournemouth Hospital a	1
Ulster Hospital	1
University College London Hospitals	2
University Hospital of North Tees, Stockton-on-Tees	1
University Hospital of Wales	1
University Hospital of Wales	1
University Hospitals Bristol NHS Foundation Trust	1
University Hospitals Southampton NHS Foundation Trust	1
Western General Hospital	2
Paediatrics	**3**
Nottingham University Hospitals NHS Trust	1

Southampton General Hospital	1
Royal Hospital for Children	1
Patient representatives	**7**
Crohns and Colitis UK	2
Patient representative	5
Primary Care	**1**
Primary Care	1
IBD Registry	**1**
Registry	1
Specialist registrar	**2**
Cambridge University Hospitals	1
St Mark's Hospital	1
Surgeons	**6**
Cambridge University Hospitals NHS Foundation Trust	1
Newcastle Royal Victoria Infirmary	1
Sheffield Teaching Hospitals NHS	1
St Mark's Hospital	1
University Hospitals Leicester	1
Worcester Acute Hospitals NHS Trust	1
Grand Total	**60**

Summary results from Round 1 of Delphi consensus survey based on the initial QI proposal

Statements are presented with the median value of responses to the 5-point Likert scale (5- strongly agree, 4 - agree, 3-neither agree nor disagree, 2 - disagree, 1 - strongly disagree) along with an interquartile range (IQR). An IQR of 2 or more suggests high level of polarity in responses.

KPI 1 –Time from primary care referral to diagnosis in secondary care

Statement	Median; IQR
Time to diagnosis is defined as weeks between referral from primary care to a documented diagnosis of IBD in secondary care.	4; 1
Documented diagnosis is defined as a formal documentation of a confirmed diagnosis of IBD in the patients' records	4; 1
Date of documented diagnosis should be left to the discretion of the clinician rather than be prescriptive based on an investigation	4; 1
Time from symptom onset to diagnosis is an important metric to measure and should form part of this KPI	4; 3
Patients diagnosed following hospitalisation should be included if a prior referral to secondary care had already been made from primary care. Data from these patients will be reported separately as an additional outcome measure for this KPI.	4; 0.5
Time from referral to time to treatment has more value as a KPI and should be preferred over KPI 1 and KPI 2. Individual IBD units will then be responsible for exploring underlying reasons for possible delays within their service.	4; 3
Delays in time to diagnosis of IBD following referral to secondary care is associated with poor clinical outcomes and quality of life measures.	4; 1
Improving time to diagnosis means that patients do not experience life changing symptoms for prolonged periods without treatment.	4; 1
Improving time to diagnosis of IBD is an important clinical priority in the current era of managing IBD.	5; 1
A minimum of 25 newly diagnosed patients is sufficient for representative benchmarking.	3; 1
A minimum of 50% of all new diagnosis should instead be used per site for representative benchmarking.	3; 2
Benchmarking time to diagnosis of IBD in secondary care can adequately represent specific modifiable organisational factors within an IBD service.	4; 0

There are no established national standards for time to diagnosis of IBD that can adopted for benchmarking	4; 1
Benchmarking diagnostic times for each IBD service in relation to national performance of IBD services is appropriate for the first round of audit	4; 1
The proposed reporting outputs of the benchmarking process is appropriate for this KPI	4; 0.75
The proposed process for QI is the appropriate for measuring and monitoring time to diagnosis from referral	4; 1
The proposed metrics (date of referral and date of documented diagnosis) are sufficiently representative for this KPI.	4; 0
There are no significant confounding factors that would impact its analysis / interpretation	2; 1
The audit process outlined is undemanding and robustly deliverable by IBD services across UK	3; 2
A defined period of data collection is not needed as this will be a rolling QI metric with near-real time KPI reporting (once minimum dataset collected) .	4; 1
Improving pathways that lead to reduction in time to diagnosis is an effective use of resources	5; 1
Reduction in time to diagnosis is feasible by IBD services across UK	4; 1
Reduction in time to diagnosis following referral will improve patient safety and outcomes	4; 1
Reduction in time to diagnosis will not negatively impact equitable access to care	4; 1.75

KPI 2 –Time to treatment recommendation following a diagnosis

Statement	**Median; IQR**
Time to treatment is defined as weeks between a documented diagnosis of IBD in secondary care to commencement of IBD specific disease modifying medical or surgical treatment	4; 1
Treatment is defined as oral or rectal mesalazine, thiopurines, biological therapies, small molecule drugs, steroids, IBD specific surgery, nutritional therapies and therapies pertaining to IBD specific clinical trials.	4; 1
First treatment of IBD started during hospitalisation can be included in this KPI. However, a documented diagnosis of IBD should not have been made on that admission unless a prior referral to secondary care had been received for secondary	4; 1

care elective service.	
Delays in time to treatment following a diagnosis of IBD is associated with poor clinical outcomes and quality of life measures	4; 1
Reduction in time to treatment following a diagnosis of IBD is currently an important clinical priority.	4; 1
A minimum of 25 newly diagnosed patients will be required to be registered per site for representative benchmarking. In order to avoid bias patients should not be pre-selected.	3.5; 1
A minimum of 50% of all new diagnosis should instead be used per site for representative benchmarking.	3; 2
Benchmarking time to initiation of treatment following a diagnosis of IBD can adequately represent specific modifiable organisational factors within an IBD service	4; 0
Standards for time to treatment following diagnosis of IBD have recently been defined in the IBD UK national report should be adopted for benchmarking rather than against national performance	4; 1
Benchmarking time to treatment following diagnosis of IBD for individual service in relation to national performance of IBD services is appropriate for the first round of audit.	4; 1
The proposed reporting outputs of the benchmarking process is appropriate for this KPI	4; 0
The proposed QI process is appropriate for measuring and monitoring time to treatment.	4; 0
The proposed metrics (date of documented diagnosis and date of treatment commencement) are sufficiently representative for this KPI.	4; 0
Data on the class of treatment should be collected in order to control for inherent delays (such as pre-screening with biologics).	4; 0
A defined period of data collection is not needed as this will be a rolling QI metric with near-real time KPI reporting (once minimum dataset collected).	4; 1
There are no major confounding factors that would impact its analysis / interpretation	3; 2
The QI process outlined is undemanding and robustly deliverable by IBD services across UK	3; 2
Improving pathways that lead to reduction in time to treatment is an effective use of resources	4; 1

Reduction in time to treatment is feasible by IBD services across UK	4; 1
Reduction in time to treatment following diagnosis will improve patient safety and outcomes	4;1
Reduction in time to treatment will not negatively impact equitable access to care	4; 1

KPI 3 – Appropriate use of steroids

Statement	**Median; IQR**
Steroid excess is defined as the prescription of 2 or more steroid courses over 12 months or > 3 months over a 12-month period.	4;1
Steroids would include any class of oral corticosteroids	4;1
Steroid use would include any given indication rather than IBD alone.	2; 2
Steroid use should measure those obtained through secondary care and primary care prescriptions as well as home supplies.	4; 1
A course of corticosteroids is defined as a minimum of at least 7 days of consecutive use	4; 1
Excessive use of steroids in IBD is associated with poor clinical outcomes and quality of life	4.5;1
Reduction in steroid use is an important clinical priority in the current era of management of IBD	4;1
Reduction of excess steroid use would mean patients overall have better disease control with reduced risk of flares and corticosteroid related side effects.	4;1
Benchmarking excess steroid use can adequately represent specific modifiable organisational factors within an IBD service	4;1
The KPI standard defined as proportion of patient's with steroid excess not exceeding 50% is appropriate.	3;2
Benchmarking for this KPI should instead be done against national performance rather than a pre-defined standard of 50%.	3;1
The proposed reporting outputs of the benchmarking process is appropriate for this KPI	4; 0.75
The proposed process for data collection is the appropriate for measuring steroid excess in patients with IBD.	4; 0
A minimum of 50 patients being prescribed steroids will be required per site for representative benchmarking.	3; 2
Excess steroid use over a 12-month period should be measured prospectively rather	4; 1

than be a retrospective snapshot for individual patients	
The proposed metrics (steroid courses and steroid duration over 12 months) are sufficiently representative for this KPI	4; 0
There are no major confounding factors that would impact its analysis / interpretation	3; 2
The audit process outlined is undemanding and robustly deliverable by IBD services across UK	3; 2
Improving pathways that lead to reduction in steroid excess is an effective use of resources	4; 1
Reduction in steroid excess is feasible by IBD services across UK	4; 1
Reduction in steroid excess will improve patient safety and outcomes	4; 1
Reduction in steroid excess will not negatively impact equitable access to care	4; 1

KPI 4 – Advanced therapies pre-screening and assessment

Statement	**Median; IQR**
Biologic pre-screening is defined as prior screening of all patients prior to starting biological / small molecule drugs based on BSG / ECCO guidelines	5;1
Biologics assessment following induction is defined as a documented review of patients between week 8 to week 20 after commencement of biological therapies that include safety and clinical and objective assessment of disease activity	4;1
Biologics assessment at one year is defined as a documented review of patients between month 10 to month 14 after commencement of biological therapies. This includes safety and clinical and objective assessment of disease activity.	4;1
Recording of disease scores / indices should form part of the assessments at both these time points.	4;1
Patient reported outcome measures should form part of the assessments at both these time points.	4;1
Documented reviews at these time points should be done by clinicians within the IBD team.	4;1
Inadequate biologic pre-screening is associated with poor clinical outcomes and quality of life scores in patients with IBD	4;1
Inadequate biologic assessment following induction maybe associated with poor clinical outcomes and quality of life scores in patients with IBD	4;1
Inadequate biologic assessment at one year after commencement maybe associated	4;1

with poor clinical outcomes and quality of life scores in patients with IBD	
Improving compliance with biologic screening and timely assessment is an important clinical priority	4;1
Benchmarking biologic screening and monitoring in secondary care can help IBD services better understand structure of their clinical service including local flare pathways	4;1
Benchmarking biologic pre-screening and assessment following induction and at one year can adequately represent specific modifiable organisational factors within an IBD service	4;1
There are no established national standards for this KPI that can adopted for benchmarking	4;1
Setting a standard of 95% for minimum proportion of patients being pre-screened prior to initiation of biologics is appropriate.	4;0
Setting a standard of 90% for minimum proportion of patients being assessed following induction of biological therapy is appropriate.	4;1
Setting a standard of 90% for minimum proportion of patients being assessed following at 1 year after biologic initiation is appropriate.	4;0
The proposed QI pathway is the appropriate for measuring biologics pre-screening and assessment of patients with IBD	4; 0
A minimum of 25 patients will be required per site for representative benchmarking	4; 1
The proposed metrics are sufficiently representative for this KPI	4; 0
There are no major confounding factors that would impact its analysis / interpretation	4; 1
The audit process outlined is undemanding and robustly deliverable by IBD services across UK	4; 1
Improving pathways that lead appropriate biologics pre-screening and safety and efficacy monitoring is an effective use of resources	4; 1
Appropriate biologics pre-screening and timely safety and efficacy monitoring is feasible by IBD services across UK	4; 1
Appropriate biologics pre-screening and safety and efficacy monitoring will improve patient safety and outcomes	4; 1
Appropriate biologics pre-screening and safety and efficacy monitoring will not negatively impact equitable access to care	4; 1

Supplementary Document 2

Delphi survey invitation for Round 2

National IBD QI initiative

Invitation to participate in Round 2 of Delphi survey

What is the national IBD Quality improvement initiative?

The delivery of inflammatory bowel disease (IBD) care is currently being reviewed by BSG in order to improve and reduce the variability of the standards of health care and quality of service that patients with IBD receive. The ability to monitor and benchmark services can help streamline pathways towards patient-centred health care, as well as guide and focus clinical service commissioning towards greater efficiency. The BSG IBD Section, IBD Registry and Crohn's & Colitis UK have joined forces to develop certain key performance indicators (KPIs) to help achieve this objective. We anticipate that this would enable IBD services to assess their performance against defined standards / national median, allow benchmarking to enable comparability across services and identify recognition of areas for improvement of the service being delivered. This process would ultimately drive change that leads to improvements in clinical outcomes, safety and experiences of patients with IBD.

What are the proposed KPIs and how have they been identified?

Through initial meetings with stakeholders including the BSG IBD Section, IBD Registry, Crohn's and Colitis UK and Royal College of Physicians the four KPIs were identified for further evaluation.

- **KPI 1 - Time from primary care referral to diagnosis in secondary care**
- **KPI 2 - Time to treatment recommendation following a diagnosis**
- **KPI 3 – Appropriate use of steroids**
- **KPI 4 – Advanced therapies pre-screening and assessment**

We proposed a two stage Delphi consensus-building approach to discuss relevance and feasibility of these KPIs along with proposed methodology for data collection, standards to assess against and how benchmarking would be performed. Round 1 successfully completed in mid-2021 with a subsequent generation of a report that was sent for review. This was followed by several meetings with stakeholders and BSG IBD section to resolve queries raised through Round 1 and further refine the QI (Quality Improvement) methodology to take to Round 2.

Why have I been invited to take part in this survey?

We recognise that the success of any QI initiative depends on continuous engagement with the QI process by IBD services. We also recognise that IBD services are variably resourced, and this may

impact on participation with QI. Traditional challenges have included variable access to electronic records, automation of data collection and lack of resource. It may also be the case that services that have not previously engaged with QI initiatives may be the ones where quality improvement is most needed to enable a positive change. Therefore, in order to achieve wide adoption, we have proposed non-burdensome data collection methodologies with collection of minimal data items for each of the KPIs.

This survey is part of a Delphi process (Round 2). With your participation we aim to explore views around relevance and local feasibility of the proposed QI initiative from a broad range of IBD services. We intend to understand if there are potential barriers to engagement with the proposed methodology and the impact the variability of resource, workforce and patient volume has on this.

How is this different to the previous and ongoing IBD audit?

Several quality and performance indicators have been developed and implemented to cover a range of areas of IBD practice in the UK over the last 15 years. The IBD Audit, established in 2004, undertook 5 rounds of national audit between 2005 to 2016 on a nearly biannual basis. This captured data on inpatient care, experiences, primary care services, organisational care and biological therapies and led to improvements that included a reduction in adult inpatient IBD mortality and time from diagnosis to commencement of treatment with biological therapies. The biological therapies aspect, including screening prior to biologics initiation and monitoring of biological therapies then transitioned to the IBD Registry which facilitated longitudinal collection and reporting of metrics around screening prior to biologics initiation and monitoring of biological therapies. In 2019 the IBD Standards were published by IBD UK, an alliance of 17 organisations working together to drive improvements in IBD care, and the IBD Patient Survey and Service Self-Assessment in 2019/2020 allowed services and patients to feedback on care against the IBD Standards. Service specific reports were published in early 2020 and those publicly available are on the IBD UK website. The national report that followed “Crohn’s and Colitis Care in the UK: The Hidden Cost and a Vision for Change” highlighted key areas that needed addressing, including delays in diagnosis, the need for quicker access to specialist advice and treatment and for more personalised and holistic care. The next round of IBD UK benchmarking will take place in early 2023 and work is currently underway to prepare for this.

These audits and benchmarking processes along with access to newer therapies, evolution of treatment targets and a shift towards patient empowerment have highlighted the real need for prospective ongoing quality assessment of IBD services. Unlike traditional audits we aim to facilitate quality improvement through prospective ongoing data collection with frequent, if not real time,

reporting of individual service performance and benchmarking. This will allow services to identify areas in need of improvement far more rapidly while seeing the impact of any positive changes made to the service through near real time performance updates.

When will the QI initiative formally commence?

Following completion of the Delphi consensus process we aim to conduct a pilot run of the KPIs across a selection of IBD services. This is likely to take place in the second half of the 2022. If successful we intend to progress to a national roll out in 2023.

Is participating in the IBD QI initiative mandatory?

At present, participation in the QI process will be voluntary. The proposed KPIs provide a window into key aspects of the patient journey through an IBD service. We anticipate that participation in this QI process will provide the ability for services to monitor and benchmark their performance through this patient journey. In turn this would help drive services towards targeted quality improvements at a local level as well as guide and focus clinical service commissioning towards greater efficiency.

How will data be collected by IBD services as part of the QI initiative?

Data may be collected either prospectively or as a snapshot retrospective audit depending on individual site preferences. Further methodology for specific KPIs is elaborated in subsequent sections of this document. Data will be collected through the tools provided by the IBD Registry who are a core part of this QI initiative. The Registry recognizes that different teams may be best served by more than one tool approach, and is expanding its data collection tools / processes to allow maximum national participation in this audit.

How will the benchmarking data be reported back to the IBD services?

Once individual services meet a set threshold for minimal number of patients that need to be reported for each KPI to enable benchmarking, they will receive a quarterly report by the IBD Registry outlining their performance against set standards and/or against a national median (defined further in later sections). The aim is for this to eventually transition to a clinical dashboard that would provide near real time access to benchmarking performance for individual services. All reports will be kept confidential and IBD services will only have access to benchmarking reports of their own performance.

Quraishi MN, *et al. Frontline Gastroenterol* 2023;0:1–8. doi: 10.1136/flgastro-2023-102409

Introductory survey questions

1. Which hospital is your IBD service based? (textbox)

2. What is the rough estimate of the IBD population that you serve? *(Under 500, 500-1000, 1000-2500, >2500; textbox)*

KPI 1 - Time from primary care referral to diagnosis in secondary care

What is the outcome measure for this KPI?

Local performance for time to a documented diagnosis of IBD following a primary care referral

How is this KPI defined?

- Time to diagnosis is defined as days between date of an appropriate referral from primary care for suspected IBD to a documented diagnosis of IBD in clinical records in secondary care.
- Documented diagnosis is defined as a formal documentation of a confirmed diagnosis of IBD in the patient's records (which may include endoscopy reports and clinical notes).
- The diagnosis of IBD would be based on the clinical judgement of the clinician, supported by a combination of assessments that may include laboratory, endoscopic, histological and radiological findings. Patients who have been referred but diagnosed following hospitalisation will be included but analysed as a sub-KPI.

What QI methodology has been proposed?

- This will be a prospective data collection of all newly diagnosed patients over a period of a year.
- This may be done at any time point of the patient's initial journey following a diagnosis; ie first outpatient or inpatient clinical review when the diagnosis is confirmed or treatment commenced.
- The aim is to capture as many patients as feasible with no defined fixed number of patients. A minimum threshold may however be set to allow benchmarking.
- IBD services that find prospective data collection challenging may consider collecting data retrospectively. It is anticipated that these sites will eventually move towards prospective and continuous data collection that will enable dynamic measurement of the service for sustained quality improvement.

What data items will be requested for each patient enrolled?

- Date of referral on the referral letter from primary care
- Date of formal documentation of a confirmed diagnosis of IBD in the clinical records
- Diagnosed as an inpatient following a following an acute (non-elective) hospital admission (yes/no)

What standards have been set for benchmarking?

Benchmarking of individual sites will be performed against the national median performance. Individual site performance will be defined as percentile / percentile rank in relation to national median. At present there is not enough evidence to define a national standard / target for time to diagnosis; however, an exploratory standard may be used for statistical analysis. Outcomes from the initial round/s of QI may be used to formally develop a national standard.

What will be reported for individual sites (benchmarking)?

The percentile for local performance will be calculated from national median performance. The local percentile rank, local median time and national median time to a documented diagnosis will be reported to individual IBD services. Diagnoses made following hospitalisation in patients with prior primary care referrals will be reported as a sub-KPI. Reports generated by IBD Registry may include visual aids such as funnel plots. It is envisaged that the initial round/s of QI will help determine national medians to help set a target waiting time that will facilitate reporting of the proportion of cases waiting above this standard. This would then be used as part of benchmarking for future rounds of QI.

Survey Questions for KPI 1

4. Is the proposed methodology for data collection feasible for your local IBD service for this KPI *(Time from primary care referral to diagnosis in secondary care)?* (*'strongly agree', 'agree', 'disagree', 'strongly disagree', 'don't know'; free text box for comments*)

5. Will your IBD service be able to use the benchmarking data provided to you for this KPI *(Time from primary care referral to diagnosis in secondary care)* to help improve the quality of care for your patients? (*'strongly agree', 'agree', 'disagree', 'strongly disagree', 'don't know'; free text box for comments*)

KPI 2 - Time to treatment recommendation following a diagnosis

What is the outcome measure for this KPI?

Local performance for time to recommendation of treatment for IBD following a diagnosis

How is this KPI defined?

- Treatment is defined as oral or rectal mesalazine, thiopurines, biological therapies, small molecule drugs, oral or rectal steroids, IBD specific surgery, nutritional therapies and therapies pertaining to IBD specific clinical trials.
- An active documented decision to watch and wait for mild disease will be considered as 'treatment' (for example in patients with mild terminal ileitis). Date treatment recommended will be recorded as *'N/A - watch and wait '*.
- Patients declining treatment would be included with date treatment recommended recorded as - *'N/A - patient declined '*.
- Advice / guidance given around management of Crohn's including advice given on smoking cessation will not count as treatment.
- For treatments commenced in secondary care – the date when the treatment was recommended will be recorded.
- For treatment recommendations made to general practice – the date when this documented recommendation was made to the GP will be recorded.
- Patients enrolled in this KPI may be invited to report on the date the treatment was initiated as part of a pilot strand of this QI process through the IBD Registry.
- Treatment commenced as an inpatient following hospitalisation (including those diagnosed on that admission) will be reported as a sub-KPI.

What QI methodology has been proposed?

- This will be a prospective data collection of all newly diagnosed patients over a period of a year.
- Patients in KPI2 should be linked to KPI1 with congruency in date of formal documentation of a confirmed diagnosis. Metrics in KPI1 and KPI2 may therefore be collected together.
- This may be done at any time point of the patient's initial journey following a diagnosis; ie first outpatient or inpatient clinical review following commencement of treatment. Clinical records may be reviewed and patients may be consulted by the clinical team to confirm dates of treatment recommendation.

- The aim is to capture as many patients as feasible with no defined fixed number of patients. A minimum threshold may however be set to allow benchmarking.
- IBD services that find prospective data collection challenging may consider collecting data retrospectively. It is anticipated that these sites will eventually move towards prospective and continuous data collection that will enable dynamic measurement of the service for sustained quality improvement.

What data items will be requested for each patient?

- Date of formal documentation of a confirmed diagnosis of IBD in the clinical records
- Date treatment recommended
- First treatment received following a diagnosis as an inpatient following an acute (non-elective) hospital admission (yes/no)

What are standards have been set for benchmarking?

As with KPI1, benchmarking of individual sites will be performed against the national median performance. Individual site performance will be defined as percentile / percentile rank in relation to national median. At present there is not enough evidence to define a national standard / target for time to treatment following diagnosis; however, an exploratory standard may be used for statistical analysis. Outcomes from the initial round/s of QI may be used to formally develop a national standard.

What will be reported for individual sites?

The percentile for local performance will be calculated from national median performance. The local percentile rank, local median time and national median time to treatment recommendation following a diagnosis will non-publicly reported to the individual IBD services. Treatment recommendation following diagnosis as an inpatient will be reported as a sub-KPI. Reports generated by IBD Registry may include visual aids such as funnel plots. An additional (non-KPI) exploratory benchmark of percentile for local performance for time to treatment initiation (based on patient reported data items) following diagnosis may be reported to these sites along with local and national median times. It is envisaged that the initial round/s of QI will help determine national medians to help set a target waiting time that will facilitate reporting of the proportion of cases waiting above this standard. This would then be used as part of benchmarking for future rounds of QI.

Survey Questions for KPI 2:

6. Is the proposed methodology for data collection feasible for your local IBD service for this KPI *(Time to treatment recommendation following a diagnosis)*? (*'strongly agree', 'agree', 'disagree', 'strongly disagree', 'don't know'; free text box for comments*)

7. Will your IBD service be able to use the benchmarking data provided to you for this KPI *(Time to treatment recommendation following a diagnosis)* to help improve the quality of care for your patients? (*'strongly agree', 'agree', 'disagree', 'strongly disagree', 'don't know'; free text box for comments*)

Quraishi MN, *et al. Frontline Gastroenterol* 2023;0:1–8. doi: 10.1136/flgastro-2023-102409

KPI 3 – Appropriate use of steroids

What is the outcome measure for this KPI?

Proportion of patients exposed to systemic steroid excess in an unselected cohort of IBD patients

What QI methodology has been proposed?

- A consecutive unselected cohort of IBD patients (regardless of prior steroid exposure) attending outpatient clinics will be invited to take part.
- A snapshot of steroid use over the prior 12 months will be assessed as per the definitions of a steroid course and metrics proposed.
- IBD services will be encouraged to capture data from a diverse range of clinical settings (that include flare and routine appointments) in order to reduce the risk of a selection bias.
- Patients enrolled may be invited to participate in a linked prospective patient reported steroid use QI process through the IBD Registry.
- The aim is to capture as many patients as feasible with no defined fixed number of patients. A minimum threshold may however be set to allow representative benchmarking.
- This methodology proposed, the definitions and standards used are adapted from the two multicentre UK audits in 2017 and 2019 (Selinger CP et al. Aliment Pharmacol Ther. 2019 Nov;50(9):1009-1018 and Selinger CP, et al. Aliment Pharmacol Ther. 2017 Nov;46(10):964-973)
- The eventual aim is to move towards a consecutive prospective clinician reported or patient reported steroid exposure data for this KPI.

How is this KPI defined?

- A course of corticosteroids is defined as a minimum of at least 7 days of consecutive use
- Steroids would include any class of oral corticosteroids including budesonide. Topical therapy in the form of steroid enemas or suppositories will not be included in this definition.
- Steroid use should measure those obtained through secondary care and primary care prescriptions as well as home supplies.
- Steroid use would include any given indication rather than IBD alone (the two multicentre national audits found only 3% of non-IBD indications met the above steroid excess definitions)
- Steroid excess is defined as the use of 2 or more steroid courses over 12 months or > 3 months over a 12-month period.
- It is important to state that not all steroid excess is inappropriate, and a second steroid course may be needed to bridge patients onto appropriate maintenance therapies. A standard for steroid

excess of no more than 15% has been set based on data from the multicentre UK audits and this will take into account such cases. Furthermore, the denominator for this KPI includes steroids exposed and unexposed patients.

- An alternative definition for appropriate steroid use based on the International Consortium for Health Outcomes Measurement (ICHOM) has also been proposed. They recommended documenting any systemic "steroid use" within the previous 12 months and whether the duration exceeded 3 months. No specific standards have been set so benchmarking on the basis of this definition would be performed against the national median.

What data items will be requested for each patient?

- Total number of courses of steroids in the last 12 months (≥0)
- Total duration (in weeks) of steroid use in the last 12 months (≥0)

What are standards have been set for benchmarking?

A standard for steroid excess of no more than 15% has been set based on data from the multicentre UK audits. Whilst inappropriate steroid excess was found in 8% of patients, it was felt this target standard may be too ambitious to achieve in the initial round of QI. Sites will be informed on how their performance compares to this standard set at 15% as well as the national average steroid excess.

What will be reported for individual sites?

The local proportion of patients with excess steroid use in an unselected cohort of IBD patients will be reported non-publicly to individual sites. The numerator to define this proportion is the total number of patients with excess steroid use and denominator is the total number of patients assessed. In addition, the local percentile rank, national median proportion of patients with steroid excess will be made available to the individual IBD services. A further non-KPI exploratory metric outlining steroid excess in steroid treated patient (numerator: total patients with steroid excess; denominator: total patients exposed to steroids) will also be reported with a view to validation for future benchmarking. Reports generated by IBD Registry may include visual aids such as funnel plots.

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Survey Questions for KPI 3:

Steroid excess is defined as the use of 2 or more steroid courses over 12 months or > 3 months over a 12-month period. As part of this definition, it is important to state that not all steroid excess is inappropriate and quite often the second course is needed to bridge a patient onto appropriate maintenance therapy. This definition as a KPI has been validated in the two multi-centre national audits and reflects evidence that correlates with good quality of care. The standards have been set taking this into account and validated as part of the national steroid audits as highlighted in the document.

8. Do you agree with the proposed definition of steroid excess? (*'strongly agree', 'agree', 'disagree', 'strongly disagree', 'don't know'; free text box for comments*)

9. Should the definition of steroid excess be revised to 3 or more steroid courses over 12 months or > 3 months over a 12-month period? Note that this is not a validated definition. (*'strongly agree', 'agree', 'disagree', 'strongly disagree', 'don't know'; free text box for comments*)

10. Is the proposed methodology for data collection feasible for your local IBD service for this KPI (Appropriate use of steroids)? (*'strongly agree', 'agree', 'disagree', 'strongly disagree', 'don't know'; free text box for comments*)

11. Will your IBD service be able to use the benchmarking data provided to you for this KPI (Appropriate use of steroids) to help improve the quality of care for your patients? (*'strongly agree', 'agree', 'disagree', 'strongly disagree', 'don't know'; free text box for comments*)

KPI 4 – Advanced therapies pre-screening and assessment

What is the outcome measure for this KPI?

Proportion of patients meeting standards for pre-treatment screening prior to initiation of advanced therapies and assessment of efficacy and safety after induction of therapy and at one year.

How is this KPI defined?

- Advanced therapies include biologics and small molecules that are used for treatment of IBD. Thiopurines and methotrexate are however excluded.
- Pre-treatment screening for infections prior to commencement of biologics is defined as per BSG guidance and includes HBV, HCV and HIV (and may include VZV if no history of chickenpox, shingles or varicella vaccination and tuberculosis screen). This may have been performed at any timepoint in patient's immunosuppression history. The interval prior to repeating these tests would be based on the clinical team's discretion. For Janus kinase inhibitors pre-treatment screening should include lipid profiles.
- Assessment of efficacy and safety following induction can be any documented review of patients between week 8 to week 20 after commencement of advanced therapies.
- Assessment of efficacy and safety at one year can be any documented review of patients between month 10 to month 14 after commencement of advanced therapies.
- The review at both these time points may be conducted by any competent member of the IBD service. The review should consider both safety and clinical parameters (including a form of patient reported outcome measure), and an objective assessment of disease activity and will only include patients who are on ongoing treatment with that advanced therapy at that time point. This review may be performed virtually, remotely or in person with the patient.

What QI methodology has been proposed?

- The process is similar to the current IBD Registry biologics audit; however with fewer data collection metrics.
- IBD services will be invited to collect defined data items as part of the KPI. Data may be collected by IBD services both prospectively and retrospectively (case note reviews) and should include patients having commenced advanced therapies from Jan 2021.
- Data will be entered following the commencement of each new advanced therapy for an individual patient. A patient may therefore have multiple entries following sequential changes to their advanced therapy. A mid-treatment switch to a biosimilar, dose optimisation, or a change in

the mode of administration of the same advanced therapy (such as intravenous to subcutaneous) would not restart that specific individual data collection episode for the patient.

- The aim is to capture as many patients as feasible with no defined fixed number of patients. A minimum threshold may however be set to allow representative benchmarking.

What data items will be requested for each patient?

- Was the patient screened for infections before starting on an advanced therapy (split by individual screening parameters)? (Yes/No)
- Was there a documented assessment of efficacy and safety between week 8 and week 20 after commencement of advanced therapy in patients with ongoing use? (Yes/No/No longer on the treatment)
- Was there a documented assessment of efficacy and safety between month 10 and month 14 after commencement of advanced therapy in patients with ongoing use? (Yes/No/No longer on the treatment)

What standards have been set for benchmarking?

- The standard for minimum expected proportion of patient's being pre-screened prior to initiation of advanced is set at 95%.
- The standard for minimum expected proportion of patient's being assessment following induction is set at 90%.
- The standard for minimum expected proportion of patient's being assessment at one year after commencement of advanced therapies is set at 90%.

What will be reported for individual sites?

The advanced therapy screening and assessment KPI will be reported to individual sites as three separate sub-KPIs each covering different aspects:

1. Screened prior to advanced therapy use (further split by individual parameters)
2. Documented assessment following induction of advanced therapy
3. Documented assessment at one year following commencement of advanced therapy

Individual IBD services will be reported on the proportion of patients that met screening and assessment criteria. Sites will be informed on how their performance compares to the pre-defined standards as well as the national average for each sub-KPI. In addition, the local percentile rank and national median proportion of patients for each sub-KPI will non-publicly made available to the individual IBD services. Reports generated by IBD Registry may include visual aids such as funnel plots.

Survey Questions for KPI 4:

13. Is the proposed methodology for data collection feasible for your local IBD service for this KPI *(Advanced therapies pre-screening and assessment)*? (*'strongly agree', 'agree', 'disagree', 'strongly disagree', 'don't know'; free text box for comments*)

14. Will your IBD service be able to use the benchmarking data provided to you for this KPI *(Advanced therapies pre-screening and assessment)* to help improve the quality of care for your patients? (*'strongly agree', 'agree', 'disagree', 'strongly disagree', 'don't know'; free text box for comments*)

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Level of engagement survey questions:

15. Does your IBD team participate in the UK IBD Registry? *(yes, no, don't know, want to/planning to)*

16. Do you think the whole of your IBD population would be adequately represented by the data you submit as part of this QI initiative (and would be measured by the KPIs)? *(yes, no, don't know)*

17. There are various ways to engage (depending on your current setup). Which of the following levels do you envisage working best for you? *(we would use the existing Registry submission tools/system setup to supply this data for KPIs/QI; we would be interested in a simple tool from the Registry focused on collecting this data for KPIs/QI; we will only be able to fill in a minimal survey).*

18. Would you be comfortable submitting patient identifiers in patients who have not explicitly consented to the Registry (This is allowed under S251 regulation / approved exemption for the IBD Registry)? *(yes, no, don't know)*

19. Do you have any final comments on this survey?

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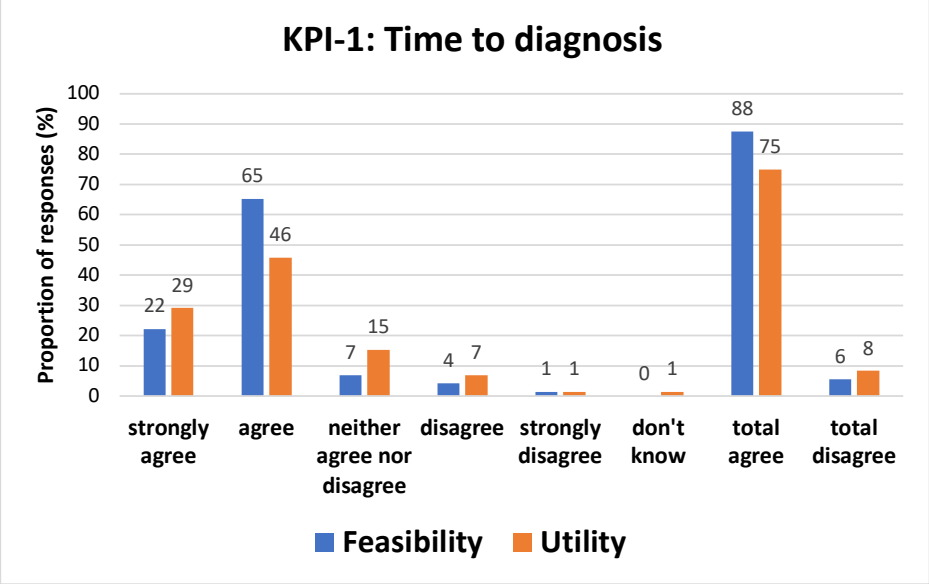
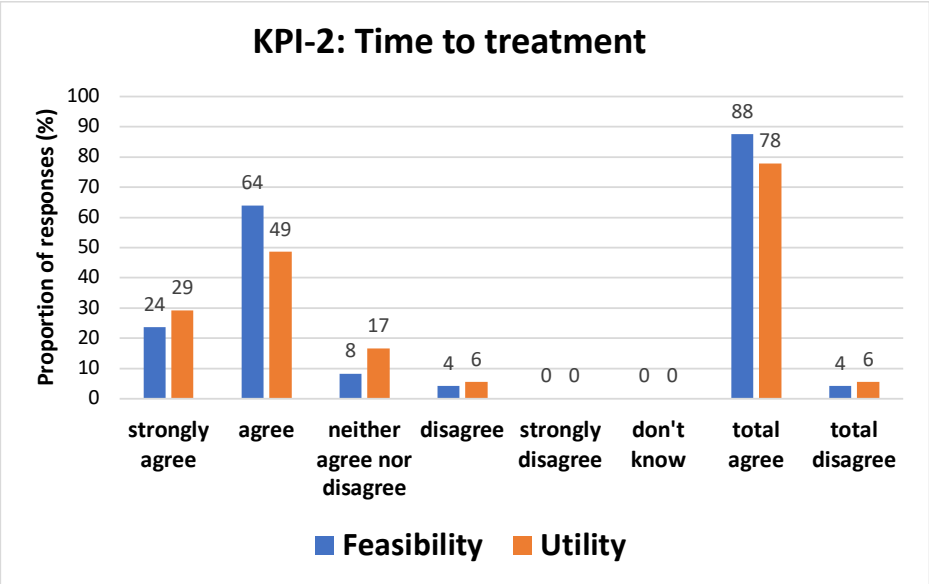
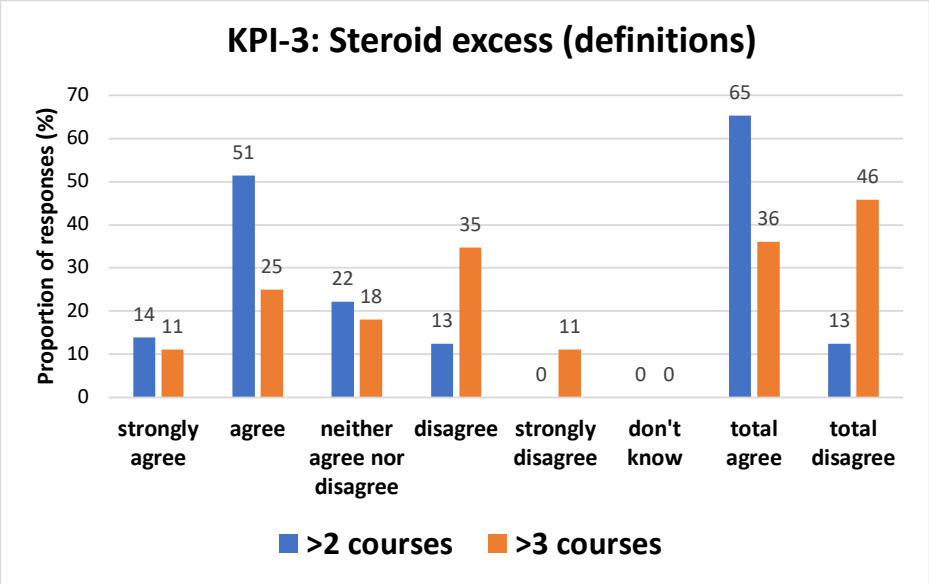
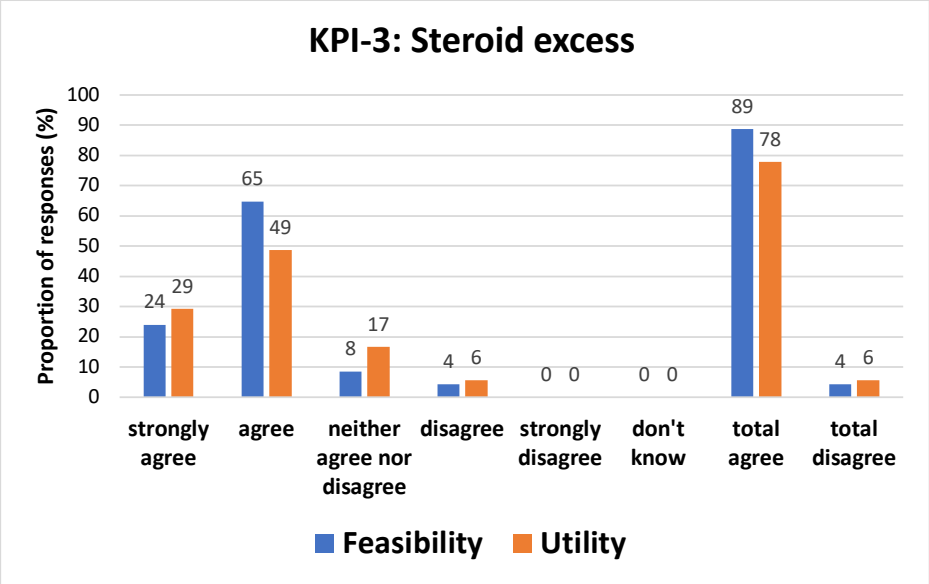
Summary results from Round 2 of Delphi consensus survey based on the updated QI proposal

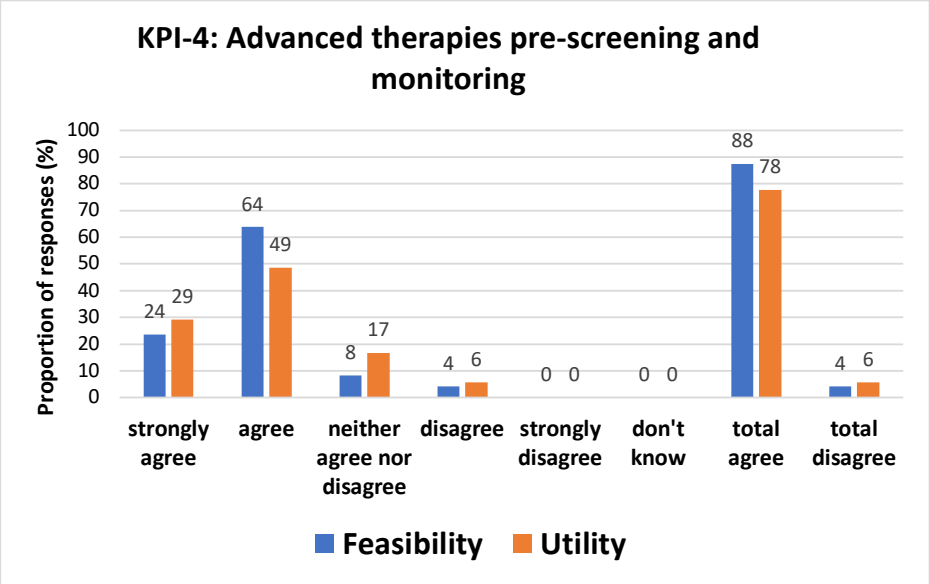
Round 2 aimed to outline opinions / challenges on local feasibility and relevance (utility) for participation in this IBD QI programme

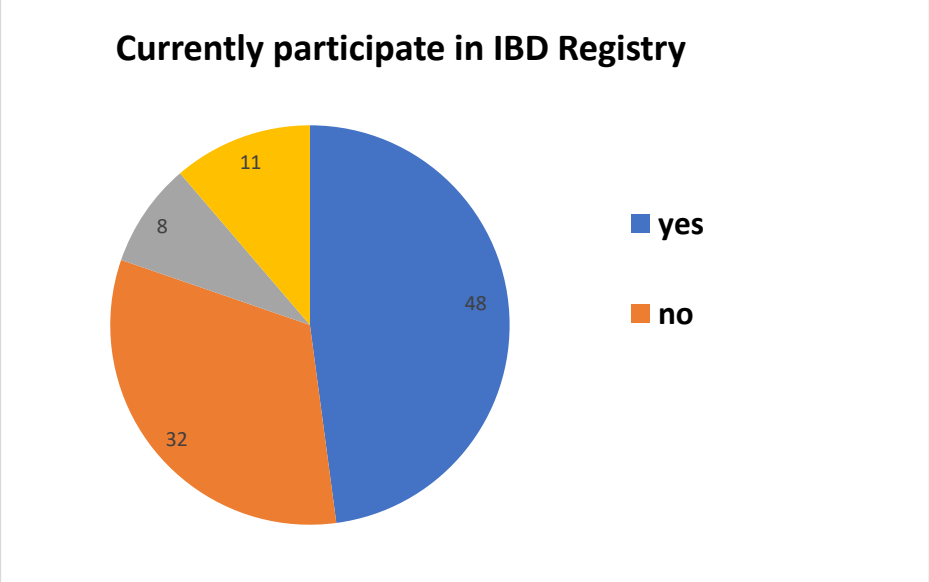


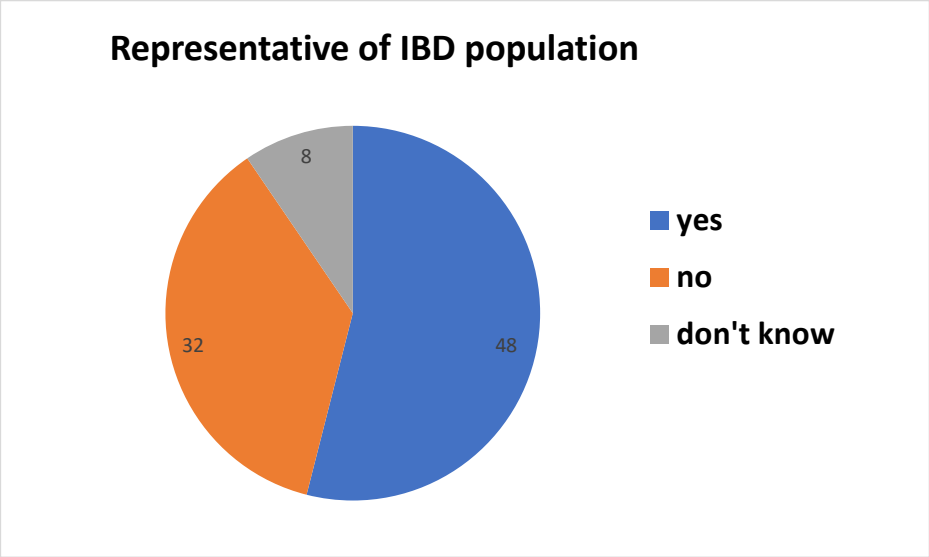


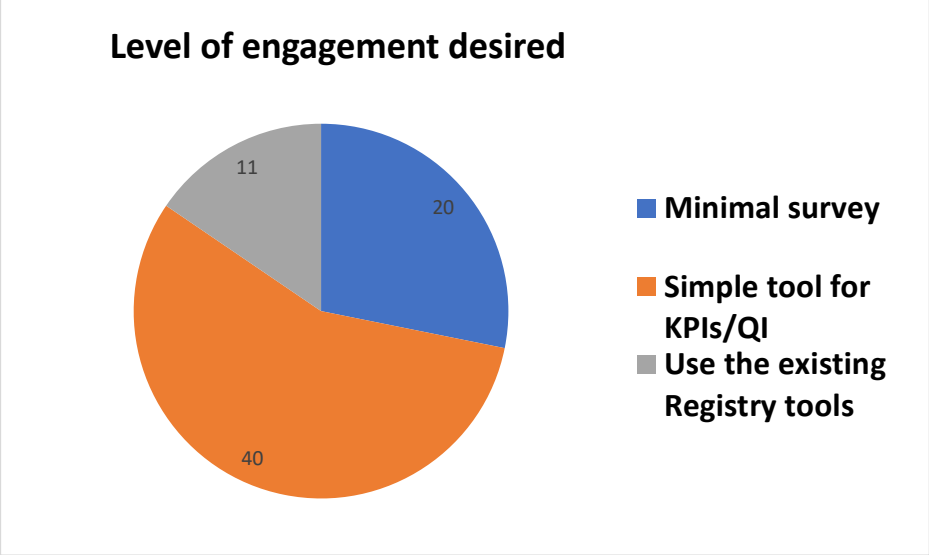

KPI-3: Steroid excess (definitions)
Proportion of responses (%)
70
60
50
40
30
20
10
0
14
11
51
25
22
18
13
35
0
11
0 0
65
36
13
46
strongly agree
agree
neither agree nor disagree
disagree
strongly disagree
don't know
total agree
total disagree
>2 courses
>3 courses


KPI-3: Steroid excess
Proportion of responses (%)
100
90
80
70
60
50
40
30
20
10
0
24
29
65
49
8
17
4
6
0 0
0 0
89
78
4
6
strongly agree
agree
neither agree nor disagree
disagree
strongly disagree
don't know
total agree
total disagree
Feasibility
Utility


KPI-4: Advanced therapies pre-screening and monitoring
Proportion of responses (%)
100
90
80
70
60
50
40
30
20
10
0
24
29
64
49
8
17
4
6
0
0
0
0
88
78
4
6
strongly agree
agree
neither agree nor disagree
disagree
strongly disagree
don't know
total agree
total disagree
Feasibility
Utility


Currently participate in IBD Registry
11
8
48
32
yes
no


Representative of IBD population
8
32
48
yes
no
don't know


Level of engagement desired
11
20
40
Minimal survey
Simple tool for KPIs/QI
Use the existing Registry tools