

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.

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)

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.

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:

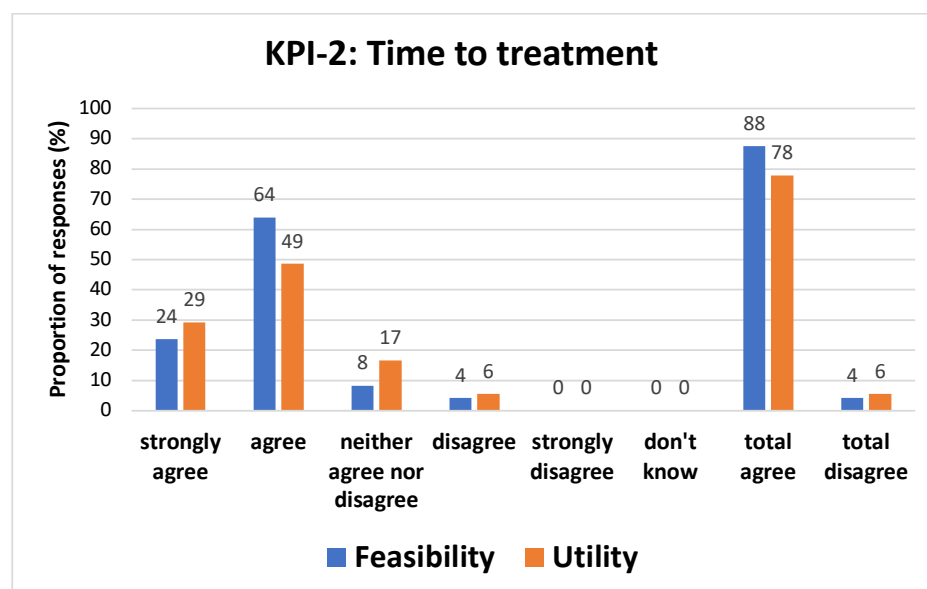
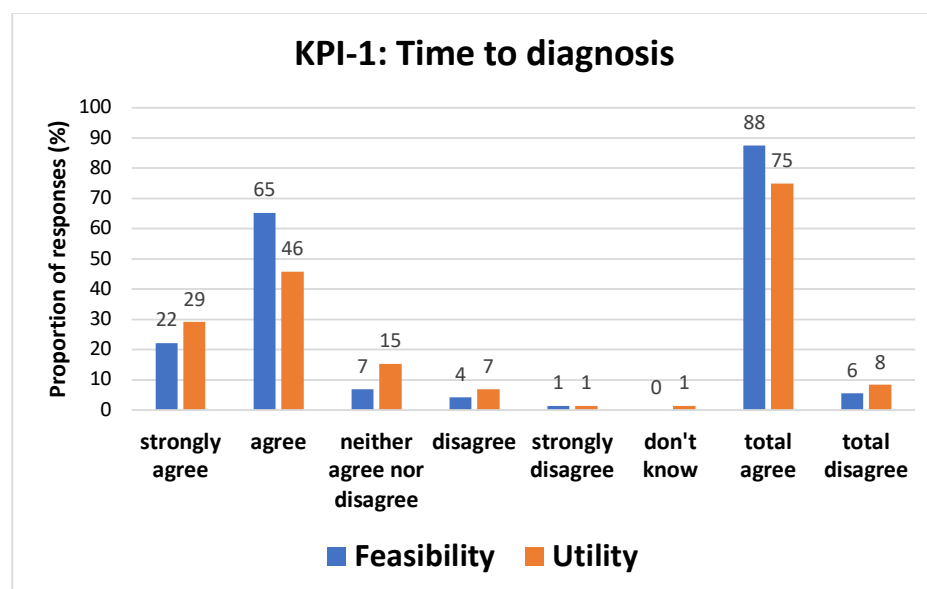
13. Is the proposed methodology for data collection feasible for your local IBD service for this KPI (*Advanced therapies pre-screening and assessment*)? ('strongly agree', 'agree', 'disagree', 'strongly disagree', 'don't know'; free text box for comments)
14. Will your IBD service be able to use the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

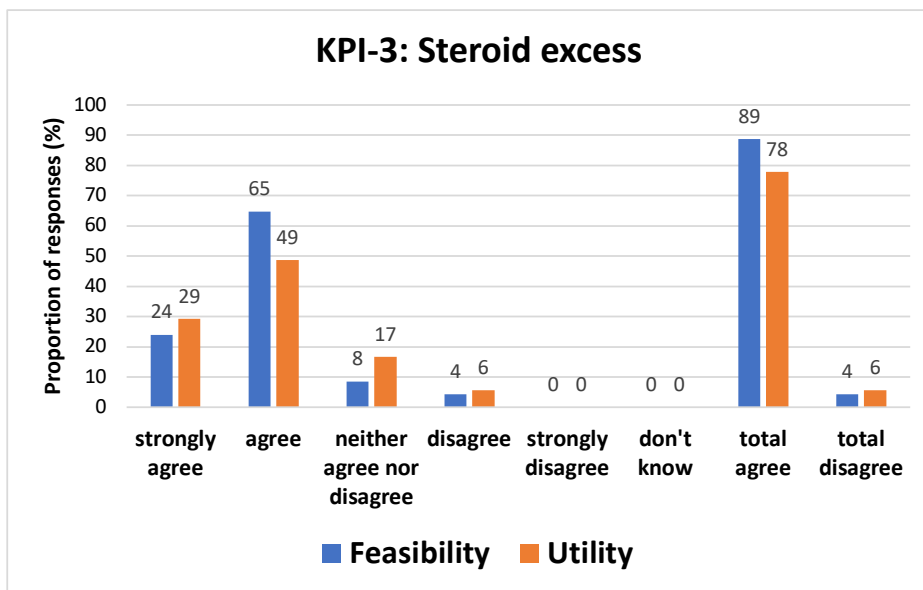
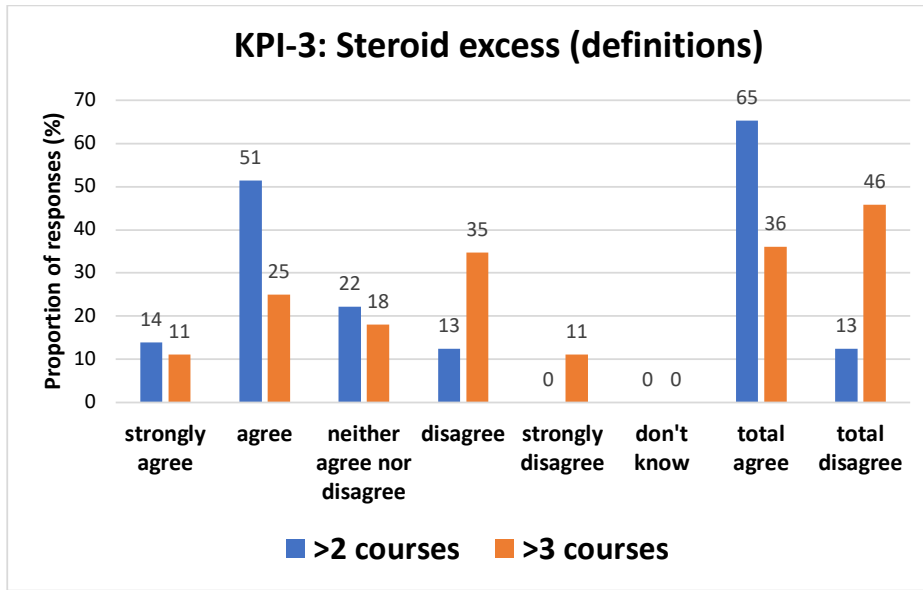
Level of engagement survey questions:

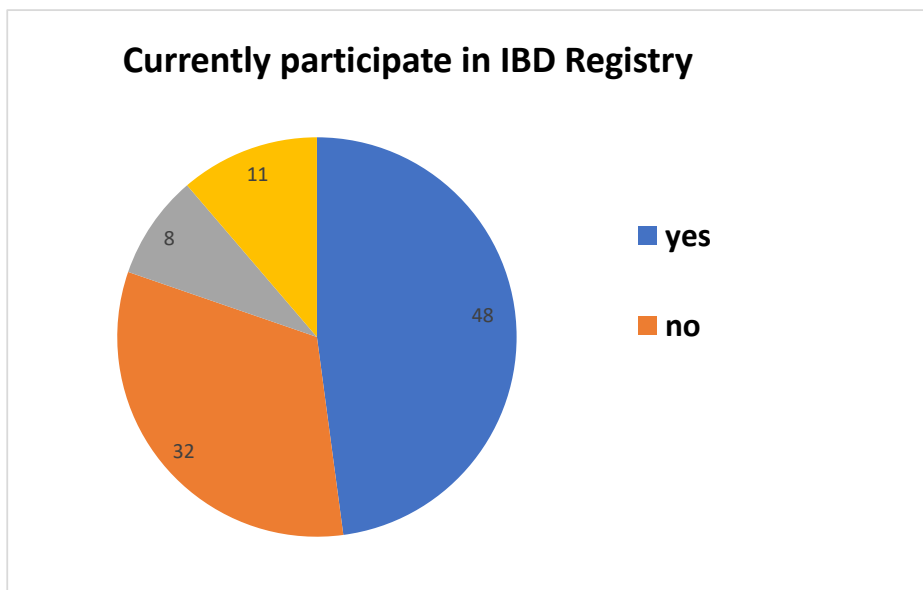
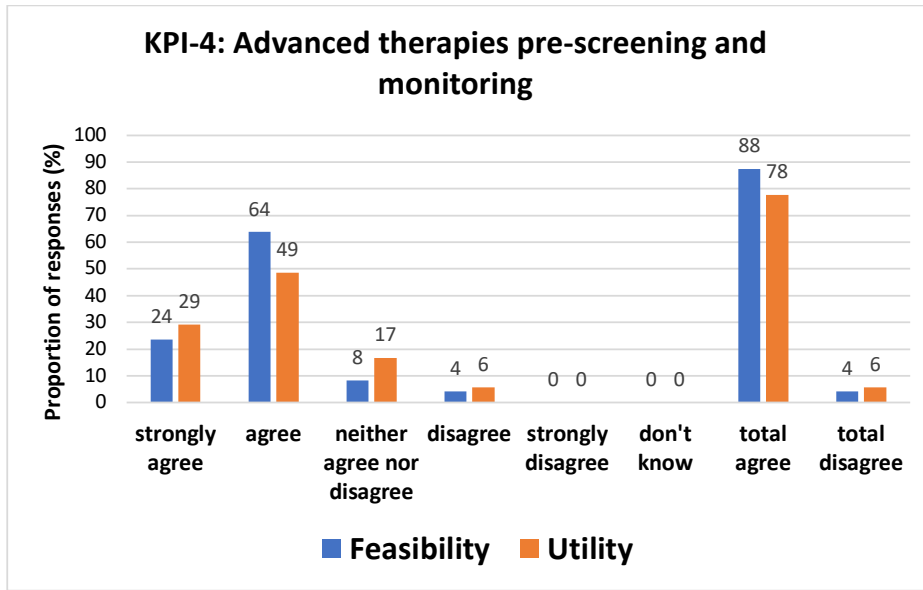
15. Does your IBD team participate in the UK IBD Registry? *(yes, no, don't know, want to/planning to)*
16. Do you think the whole of your IBD population would be adequately represented by the data you submit as part of this QI initiative (and would be measured by the KPIs)? *(yes, no, don't know)*
17. 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?

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

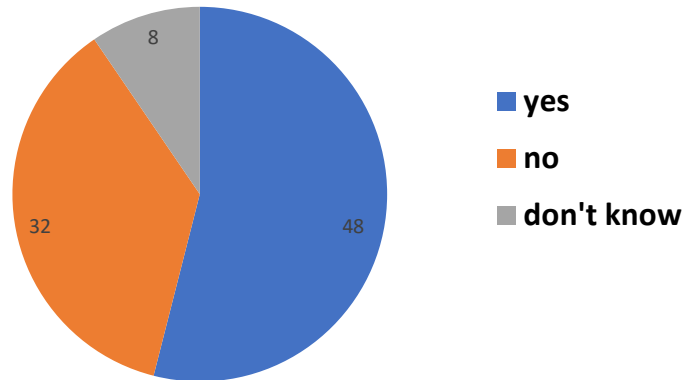
Round 2 aimed to outline opinions / challenges on local feasibility and relevance (utility) for participation in this IBD QI programme







Representative of IBD population



Level of engagement desired

