NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION SUMMARY REPORT

1 Quality standard title

Inflammatory bowel disease

Date of Quality Standards Advisory Committee post-consultation meeting:
23 June 2014.

2 Introduction

The draft quality standard for inflammatory bowel disease was made available on the NICE website for a 4-week public consultation period between 30 April and 30 May 2014. Registered stakeholders were notified by email and invited to submit consultation comments on the draft quality standard. General feedback on the quality standard and comments on individual quality statements were accepted.

Comments were received from 27 organisations, which included service providers, national organisations, professional bodies and others.

This report provides the Quality Standards Advisory Committee with a high-level summary of the consultation comments, prepared by the NICE quality standards team. It provides a basis for discussion by the Committee as part of the final meeting where the Committee will consider consultation comments. Where appropriate the quality standard will be refined with input from the Committee.

Consultation comments that may result in changes to the quality standard have been highlighted within this report. Comments suggesting changes that are outside of the process have not been included in this summary. The types of comments typically not included are those relating to source guidance recommendations and suggestions for non-accredited source guidance, requests to broaden statements out of scope, requests to include thresholds, targets, large volumes of supporting information, general comments on the role and purpose of quality standards and requests to change NICE templates. However, the Committee should read this summary alongside the full set of consultation comments, which are provided in appendices 1 and 2.

3 Questions for consultation

Stakeholders were invited to respond to the following general questions:

1. Does this draft quality standard accurately reflect the key areas for quality improvement?

2. If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures?

Stakeholders were also invited to respond to the following statement specific questions:

1. For draft quality statement 2: At the Quality Standards Advisory Committee meeting, the committee discussed the importance of support for people with inflammatory bowel disease (for example, from dietitians and specialist nurses). This statement includes the concept of individualised care and support. Have we captured the important element of patient support in this draft statement and its definitions?

2. For draft quality statement 5: This is a ‘developmental’ quality standard statement relating to an emerging diagnostic technology. As a developmental statement it may be expected that it will be implemented over a longer timescale than the other statements in this quality standard because changes to patterns of service delivery may need to be put in place. Do you agree that the statement:

- represents an emergent area of practice that is only currently being carried out by a minority of providers and
- needs specific, significant changes to be put in place and
- has the potential to be widely adopted and therefore drive improvement in outcomes?

4 General comments

The following is a summary of general (non-statement-specific) comments on the quality standard.

- General support for the draft quality statements on inflammatory bowel disease.
- Concerns were raised about the exclusion of people with indeterminate colitis from the quality standard and it was felt that the quality standard should apply to all people with IBD or suspected IBD. The inappropriate use of this term was also raised and “inflammatory bowel disease, unclassified” was suggested instead.
- The absence of histopathology in the quality standard was raised.
- The importance of a specialist IBD nurse needs to be highlighted throughout the document.
- Suggestions for overarching indicators were made.
- The need for the quality standard to reflect and refer to the IBD Standards was raised.
- Five statements were considered inadequate to meaningfully cover all aspects of care for this complicated topic.

Consultation comments on data collection

- Of the limited responses to this question, two stakeholders felt that data collection is possible if the systems and structures are available.
- Difficulties in data collection were highlighted due to systems not being in place. Explicit support for a registry is needed in the quality standard to aid collection of denominator data.
- The role of the IBD Audit was highlighted for monitoring provision against the quality standard and stakeholders felt it should be cited as a data source throughout the quality standard.
- IBD services should keep a local register of all people with a diagnosis of IBD and secondary care facilities that treat IBD should support and implement data collection on IBD through the BSG IBD registry and other local and national cohort databases.

5 Summary of consultation feedback by draft statement

5.1 Draft statement 1

People with suspected inflammatory bowel disease are referred for specialist assessment and investigation using agreed local referral pathways.

Consultation comments

Stakeholders made the following comments in relation to draft statement 1:

- There needs to be more detail regarding the specifics of the referral and interventions involved in 'local referral pathways' and minimum standards should be set to ensure pathways are efficient and reduce the rates of unnecessary referrals. Suggestions for further details include:
  - a timeframe for referral.
  - defining the term 'specialist' and highlighting the role of the specialist multidisciplinary team within an IBD service during diagnosis.
  - how to differentiate between people with suspected IBD and other gastrointestinal conditions, such as GPs using faecal calprotectin testing.
  - local access to MRI in the assessment of the small bowel in Crohn's disease as part of the investigations for IBD.
  - referring patients to a unit which has good outcome data and which participates in the IBD audit or sends data to registries where they exist.
- The incorrect use of 'indeterminate colitis' and exclusion of people with forms of microscopic colitis (people with chronic non bloody diarrhoea) and types of colitis caused by radiotherapy or use of NSAIDs was raised. People with diarrhoea for 6 weeks without rectal bleeding should also be considered as having suspected IBD.
- Including the elements of patient experience that should be measured in the outcome measure.
- Consider splitting the statement into two, with one statement on identification and referral and another on assessment.

- There are primary care facilities where GPs carry out diagnostic tests, such as endoscopic assessments, at their practices and a growing number of patients are managed completely in primary care.

5.2 Draft statement 2

People with inflammatory bowel disease, and their family members or carers (as appropriate), are supported to agree age-appropriate treatment options and monitoring arrangements with their responsible clinician.

Consultation comments

Stakeholders made the following comments in relation to draft statement 2:

- There was general support for a statement on a patient-centred approach.
- This statement encompasses too many aspects of care and could be split into separate statements on annual review/ongoing monitoring for the complications of IBD, patient information and support and age-appropriate care (including recording of pubertal status, targeted information and transition to adult services).
- Suggestions for further details and clarification needed were:
    - rapid access to specialist advice when needed and early detection of relapse.
    - clarification of age-appropriate treatment options and specific reference to paediatric treatment. Otherwise this may lead to treatment choices being based on an adults' age when lifestyle, treatment goals and risks of each treatment option would be more appropriate factors to consider than age alone.
    - written care plans and self-management and an emphasis on the importance of patient choice and empowerment.
    - greater emphasis on the assessment and treatment of anaemia as part of IBD monitoring.
    - clarify that dietetic and nursing support is from professionals with gastroenterology/IBD expertise.

  - adequate cover should be provided at all times from dietetic and nursing support within the multidisciplinary team.
  - include the role of the specialist pharmacist in the definition of the multidisciplinary team.
  - highlight the importance of patient access to someone they can discuss the impact of IBD on work/education with.
  - MRI as a means of monitoring Crohn's disease.
  - include further detail on the role of the GP in long-term care as the majority of IBD patients are managed in primary care.
- These aspects of care are better being arranged at a local level.
- Stakeholders provided suggestions for additional outcome measures:
  - Proportion of patients provided with adequate information (patient-reported).
  - Proportion of IBD patients aged <16 looked after in an adult IBD service.
  - Proportion of IBD patients with iron-deficiency anaemia, treated with iron.
  - Proportion of patients on a thiopurine that have their bloods monitored at least 3 monthly.

Consultation question 3

Stakeholders made the following comments in relation to consultation question 3:

- Nutritional assessment and support, identification and treatment of micronutrient deficiency, particularly iron deficiency, and psychological support for children and adolescents should be mentioned specifically.
- Patients and families should also be educated about the risk of developing arthritis.
- Patient support has been covered but the importance of a specialist nurse needs to be referred to more throughout the quality standard.

5.3 Draft statement 3

People with inflammatory bowel disease who need surgery have it undertaken by a colorectal surgeon in a unit where the operations are performed regularly.

Consultation comments

Stakeholders made the following comments in relation to draft statement 3:

- There was support for this statement but it needs to be added to and certain aspects more clearly defined. The following suggestions to achieve this were made:
  - expanding “by a colorectal surgeon” to “by a colorectal surgeon with experience in IBD surgery”.
  - replacing “performed regularly” with “performed frequently” and defining this as “surgical units undertaking common conventional and laparoscopic IBD surgery frequently. For ileoanal pouch surgery units performing at least 10 cases (for example, ileo-anal pouch procedures) per year as a minimum”.
  - specifying that colorectal surgeons must be a core member of a multidisciplinary IBD team and perform IBD surgery frequently.
  - stating that surgical units should be units where 2 or more colorectal surgeons are present and are supported by at least 2 consultant gastroenterologists. There should also be access to a colorectal surgeon to perform emergency colectomies.
  - units performing IBD surgery should offer multidisciplinary support and record and audit data, such as the nature of surgeries performed and outcomes data (immediate and delayed complications and referral for medical follow up).
  - the term indeterminate colitis should not be used and instead the term “IBD with a colonic phenotype” or “IBD unclassified” should be used.
  - including pre-operative histology assessment by an expert histopathologist.
- An additional outcome measure was suggested: Proportion of patients with ‘good’ or ‘adequate’ results following pouch surgery (patient-reported).

5.4 Draft statement 4

People with inflammatory bowel disease who are receiving drug treatment have the response to treatment monitored and are offered other treatment options if needed.

Stakeholders made the following comments in relation to draft statement 4:

- There was support for the statement but stakeholders felt it needs clearer wording, more detail around who takes clinical responsibility for monitoring and should include review and assessment of disease severity whatever type of therapy the patient is receiving.
- The inclusion of timeframes for monitoring arrangements and the assessment of the efficacy of treatment were suggested.
- Shared care protocols between primary and secondary care for medication prescribing and monitoring should be included.
- Patient Reported Outcome Measures could be used to monitor disease severity and quality of life.
- The role of the specialist pharmacist in managing treatment was highlighted.
- Allowing patients to self-manage is not mentioned and discretionary support is often used in IBD services.
- Patient adherence to therapy is key to successful treatment of IBD and should also be monitored.
- The importance of involving patients in treatment monitoring and listening to their concerns was raised.
- Outcomes for patients receiving biological therapies should be submitted to the UK IBD biological therapies audit.

5.5 Draft statement 5 – developmental quality statement

Adults with recent-onset lower gastrointestinal symptoms for whom specialist assessment is being considered (and in whom cancer is not suspected), and children with suspected inflammatory bowel disease who have been referred for specialist assessment, are offered faecal calprotectin testing.

Consultation comments

Stakeholders made the following comments in relation to draft developmental statement 5:

- There was support on the whole for the use of faecal calprotectin testing.
- Some stakeholders felt that this test is not 'cutting edge' and the evidence base is well established and therefore the statement should be a standard statement and not developmental. They felt this statement should be used to drive the routine use of this diagnostic tool as part of best clinical practice. An opposing opinion was that guidance on this test is conflicting (strongly advocated by some and said to be inadequately evaluated by others).
- A timeframe for referral of patients where clinical symptoms and faecal calprotectin indicate a risk of IBD should be included.
- More research is needed to guide better implementation of faecal calprotectin tests.
- Concerns were raised that the test does not pick up patients with microscopic colitis and they may be mistakenly identified as having IBS, which would lead to delays in testing and diagnosis.
- This test was felt to be of less value to people over 50 as colorectal cancer is more common amongst this group.
- Suggestions were made to incorporate the use of faecal calprotectin tests into another statement, such as statement 1 or statement 4, rather than have it as a separate statement.

Consultation question 4

Stakeholders made the following comments in relation to consultation question 4:

- Of the few responses received, the majority of stakeholders agreed with the consultation questions and feel the test could be widely adopted.
- One stakeholder disagreed that there is a need for significant changes to be made to implement the test.
- The test was said to be rarer in primary care but increasingly common in secondary care.
- A need for change in coordinating the funding of diagnostic pathways between primary and secondary care was raised.
- Concerns were raised about the reliability of the test and one stakeholder felt that the test is under-used as it remains suboptimal: there is a wide range of normal values and disagreement about appropriate thresholds. Further research was suggested.
- The test might underestimate the chance of patients having microscopic colitis or Crohn’s disease.

6 Suggestions for additional statements

The following is a summary of stakeholder suggestions for additional statements.

- A statement to exclude infective causes of diarrhoea, including Clostridium difficile (particularly in patients who have recently had antibiotics).
- An additional statement on nutritional assessment and support.
- Psychological support, in particular for children and adolescents, was recommended as a priority area.
- Stakeholders felt that access to innovative treatments and clinical research for people who do not respond to conventional therapy should be considered as an improvement area.

Appendix 1: Quality standard consultation comments table (external)

ID	Stakeholder	Statement No	Comments[1]
1	Abbvie	General	AbbVie suggests that an additional statement should be added requiring the provision of a shared care guideline between primary and secondary care to be in place for IBD. This statement should give recommendations on the minimum content to be addressed, including referral, patient education, prescribing and monitoring of conventional therapies, management of relapse, monitoring for patients on biologic therapies and rapid access to a specialist if required.
2	Abbvie	General	We propose an additional statement requiring a written personal care plan to be provided to patients with IBD
3	Abbvie	General	We propose an additional statement requiring data collection and audit of the outcome measures outlined in Quality statement 4 to monitor the outcomes achieved in IBD
4	Abbvie	General	We would suggest adding the following key outcomes: Improving quality of life Reducing burden of disease on patients' and their families. We would suggest amending work absenteeism to improving 'work productivity' as IBD can lead to work productivity losses through absenteeism, presenteeism (reduced productivity while at work) and labour market participation (working part time or retiring early due to IBD)[2]. Therefore, the impact of IBD on work productivity is broader than work absenteeism alone. The same can be said for productivity in terms of education as IBD can lead to reduced productivity while at school as well as days off school.
5	Bladder & Bowel Foundation	General	This Quality Standard is much needed. Sufferers of Inflammatory Bowel disease often report that they do not receive coordinated care. It is also often reported via the Bladder & Bowel Foundation that access to conservative management and support systems varies widely across the country. Consequently, sufferers are often misdiagnosed, undiagnosed or self-diagnosed resulting in poor management and a catastrophic impact on both school and the

[1] PLEASE NOTE: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how quality standards are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its staff or its advisory committees.
[2] Gay M et al. Crohn's Colitis and Employment – from Career Aspirations to Reality. Hertfordshire: Crohn's and Colitis UK, 2011.

ID	Stakeholder	Statement No	Comments[1]
			workplace.
6	Bonpharma Ltd	General	As the QS is likely to be used and referred to by those both commissioning and providing services to patients with IBD it is important that the QS's highlight in more detail some of the specifics regarding referral and interventions rather than relying upon "agreed local referral pathways".
7	Bonpharma Ltd	General	Widely supported IBD standards already exist and it would be helpful to make reference to these. Eg http://www.ibdstandards.org.uk/uploaded_files/IBDstandards.pdf
8	British Infection Association	General	We would welcome a statement about the need to exclude infective causes of diarrhoea, including Clostridium difficile (particularly in patients who have recently had antibiotics).
9	British Society of Gastroenterology	General	Whilst it is appreciated that the number of statements should be kept to a minimum the scope of the standard is extensive and it is felt that five statements are inadequate to fully appraise all aspects of care. The standards produced by the IBD Standards Committee covered care at a minimum level but the proposed NICE standards seem to have lowered the thresholds (e.g. the surgical standards). There is concern that this will result in some of the standards becoming less meaningful.
10	British Society of Paediatric and Adolescent Rheumatology	General	I don't think there is reference to the important association of chronic arthritis with inflammatory bowel disease in children and adults. Studies show arthritis occurs in up to 26% of people with Crohn's disease[3]. Arthritis can include a transient arthritis linked to flare of inflammatory bowel disease, but also can include a more independent chronic polyarthritis or ankylosing spondylitis. Inflammatory bowel disease can present as chronic arthritis, with joint symptoms sometimes clearer than gastrointestinal concerns until significant time down the line. Studies investigating for Crohn's disease in patients with arthritis should be considered[4] when advising what symptoms should be investigated for inflammatory bowel disease and how. Perhaps more so in children, joint symptoms in children with inflammatory bowel disease from arthritis are often under-reported or overlooked, with the diagnosis of arthritis often delayed.

[3] Holden W, Orchard T, Wordsworth P. Enteropathic arthritis. Rheum Dis Clin N Am 2003;29:513-30.
[4] Danda D, Kurien G, Chacko A, Chandy G, Patra S, Mathew A, et al. Crohn's Disease in Rheumatology clinic – An Indian Experience. J Postgrad Med 2005;51:269-74.

ID	Stakeholder	Statement No	Comments[1]
			I think this should be highlighted and consideration of whether routine screening of joints at diagnosis and eg annually using the validated pGALS examination system[5].
11	Crohn's and Colitis UK	General	We fully support the IBD Standards Group response. In general, we feel that the draft quality standard covers the areas that are important to people with inflammatory bowel disease in terms of the treatment and care that they receive. We particularly welcome the recognition of establishing prompt diagnosis, providing patient information and support with individualised, person-centred care and ensuring essential ongoing monitoring for everyone with inflammatory bowel disease. There have been significant improvements in IBD services and care since the first UK IBD Audit in 2006 and the first all-age audit in 2008. However, there is still considerable variation in services and deficits in specific aspects of provision, for example, in relation to access to dietitians for adults and psychological support. This quality standard should make it clear to people with inflammatory bowel disease what they can expect from their local health service. It also has the potential to drive quality improvement in IBD care, especially if it reflects the existing Standards for the Healthcare of People who have Inflammatory Bowel Disease (IBD Standards), which were produced in 2009 and updated in 2013 by the IBD Standards Group of patient and professional organisations. Crohn's and Colitis UK chairs the IBD Standards Group and has been fully involved in the development of the IBD Standards, ensuring that they are patient-centred and underpinned by patient experience, needs and wishes. The role of the UK IBD Audit, in our view, has been fundamental to the positive shift in IBD care and we believe it is the natural vehicle for monitoring provision against this quality standard in the future. As an existing data source which is currently part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP) and reported in the Quality Accounts, we believe the UK IBD Audit should be cited as a data source throughout the quality standard, as in other related quality standards for similar audits (for example, QS54: Faecal Incontinence).

[5] Foster HE et al. Musculoskeletal screening examination (pGALS) for school-age children based on the adult GALS screen. Arthritis Rheum. 2006 Oct 15;55(5):709-16.

ID	Stakeholder	Statement No	Comments[1]
			To attempt to cover the whole of this complicated area of care in five main quality statements is clearly not possible to do in a meaningful way. In order to ensure the quality standard is effective, the statements need to be more tightly defined and, in the case of quality statement 2, separated out into more than one statement. In our comments below, we suggest how we feel this could be addressed with reference to what we have learned directly from patients, using illustrative quotes throughout. These are shown in italics.
12	Crohn's and Colitis UK	General	The draft quality standard refers to the topic overview which states that people with indeterminate colitis will not be covered. It is our strongly held view that a quality standard for inflammatory bowel disease should apply to everyone with inflammatory bowel disease or suspected inflammatory bowel disease. It is confusing and unhelpful to exclude this group* and makes no practical sense in terms of the specific quality statements and service delivery. For people who have been diagnosed with indeterminate colitis or IBD unclassified, it is likely that they will have some concerns or possible anxieties about this diagnosis and what it means for them. To directly exclude them from the scope of this quality standard could serve to exacerbate these. In deciding to pursue a quality standard which covers IBD rather than Crohn's Disease or Ulcerative Colitis specifically, we believe it is both logical and essential that the quality standard applies to everyone with IBD. *The *BSG Guidelines* state that "About 5% of patients with inflammatory bowel disease affecting the colon are unclassifiable after considering clinical, radiological, endoscopic and pathological criteria, because they have features of both conditions [Crohn's Disease and Ulcerative Colitis] This is now termed as 'IBD, type unclassified (IBDU)'. The term 'Indeterminate Colitis {IC)' should be reserved for cases where colectomy has been performed and the pathologist remains unable to classify the disease after a full examination."
13	Department of Health	General	I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.
14	Digital assessment service, NHS Choices	General	DAS welcome the guideline and have no comments on its content.

ID	Stakeholder	Statement No	Comments[1]
15	IBD Standards Group	General	In general, we feel that the draft quality standard covers the right areas. We particularly welcome the recognition of the importance of establishing prompt diagnosis, providing patient information and support with individualised, person-centred care ensuring essential ongoing monitoring for everyone with inflammatory bowel disease. We have seen significant improvements in IBD services and care since the first UK IBD Audit in 2006 and the first all age audit in 2008. However, there is still considerable variation in services and deficits in specific aspects of provision, for example, access to dietitians for adults and psychological support. This quality standard has the potential to provide further impetus for and drive quality improvement in IBD care, especially if it reflects the existing Standards for the Healthcare of People who have Inflammatory Bowel Disease (IBD Standards), which were produced in 2009 and updated in 2013 by the IBD Standards Group of patient and professional organisations. The role of the UK IBD Audit, in our view, has been fundamental to the positive shift in IBD care and we believe it is the natural vehicle for monitoring provision against this quality standard in the future. The IBD Registry is also critical to building our knowledge of IBD and informing the future delivery of good quality care. It is envisaged that the UK IBD Standards Group, IBD Audit and IBD Registry will work closely to provide integrated data collection, analysis and quality improvement. As an existing data source which is currently part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP) and reported in the Quality Accounts, we believe the UK IBD Audit should be cited as a data source throughout the quality standard, as in other related quality standards for similar audits (for example, QS54: Faecal Incontinence. In order to ensure the quality standard is effective, the statements need to be more tightly defined and, in the case of quality statement 2, separated out into more than one statement. To attempt to cover the whole of this complicated area of care in five main quality statements is clearly not possible to do in a meaningful way. In our comments below, we suggest how we feel this could be addressed.
16	IBD Standards Group	General	The draft quality standard refers to the topic overview which states that people with indeterminate colitis will not be covered. It is our strongly held view that a quality standard for inflammatory bowel disease should apply to everyone with inflammatory bowel disease or suspected inflammatory bowel disease. It is confusing and unhelpful to exclude this group* and makes no practical sense in terms of the specific quality statements and service delivery.

ID	Stakeholder	Statement No	Comments[1]
			*The *BSG Guidelines* state that "About 5% of patients with inflammatory bowel disease affecting the colon are unclassifiable after considering clinical, radiological, endoscopic and pathological criteria, because they have features of both conditions [Crohn's Disease and Ulcerative Colitis] This is now termed as 'IBD, type unclassified (IBDU)'. The term 'Indeterminate Colitis {IC)' should be reserved for cases where colectomy has been performed and the pathologist remains unable to classify the disease after a full examination."
17	NHS England	General	Thank you for the opportunity to comment on the consultation for the above Quality Standard. I wish to confirm that NHS England has no substantive comments to make regarding this consultation.
18	Nutricia Advanced Medical Nutrition	General	In relation to the statement, 'The efficacy of EEN to treat active Crohn's disease has not been assessed in controlled studies against normal diet', I would like to propose that the studies below are acknowledged and the results summarised, in order to show that this evidence has been considered and that the results of these trials have been interpreted: Riordan AM, Hunter JO, Cowan RE et al. Treatment of active Crohn's disease by exclusion diet: East Anglian Multicentre Controlled Trial. The Lancet 1993;342:1131-1134. Park R, Galloway A, Russell RJ. Double blind controlled trial of elemental and polymeric diets as primary therapy in active Crohn's disease. Eur J Gastroenterol Hepatol 1991;3:483-490. O'Morain C, Segal AW, Levi AJ. Elemental diet as primary treatment of acute Crohn's disease: a controlled trial. BMJ 1984:288:1859-1862. I have not summarised the methodology and results of these papers, but would be happy to do so if this was required and appropriate.
19	Royal College of Pathologists	General	The document is well written and clear. There is very little mention of histopathology, but this may be intentional given the nature and scope of the paper. I am happy to add pathology comments if required. Also, some of the current pathology guidelines might be worth referencing, but again this may not be relevant to the target audience.
20	Royal College of Physicians.	General	The RCP is grateful for the opportunity to respond to the draft quality standard and wishes to fully endorse the responses submitted by the British Society of Gastroenterology and the IBD Standards Group. Overall, we particularly wish to emphasise that five statements are felt inadequate to fully appraise all aspects of care in this area. More detailed comments follow.

ID	Stakeholder	Statement No	Comments[1]
			In general, we feel that the draft quality standard covers the right areas. We particularly welcome the recognition of the importance of establishing prompt diagnosis, providing patient information and support and individualised, person-centred care and ensuring essential ongoing monitoring for everyone with inflammatory bowel disease. We have seen significant improvements in IBD services and care since the first UK IBD Audit in 2006. However, there is still considerable variation in services and deficits across the board in specific aspects of provision, for example, access to dietitians for adults and psychological support for all. This quality standard has the potential to provide further impetus for and drive quality improvement in IBD care, especially if it reflects the existing Standards for the Healthcare of People who have Inflammatory Bowel Disease (IBD Standards), which were produced in 2009 and updated in 2013 by the IBD Standards Group of patient and professional organisations. The role of the UK IBD Audit in our view, has been fundamental to the positive shift in IBD care and we believe it is the natural vehicle for monitoring provision against this quality standard in the future. It is envisaged that the UK IBD audit will work closely with the IBD Registry and IBD Standards group to provide seamless data collection, analysis and quality improvement. We feel that the UK IBD audit should be cited as a data source where relevant throughout the report, as is the case in other quality standards for example QS54-Faecal incontinence (http://publications.nice.org.uk/faecal-incontinence-qs54/quality-statement-4-initial-management). Alternatively it could be included in the list of data sources included on page 22/38 in the current draft. In order to ensure the quality standard is effective, we feel the statements require more specificity to support the development of quality services and in the case of quality statement 2, separated out into more than one statement. To attempt to cover the whole of this complicated area of care in four main quality statements is clearly not possible to do in a meaningful way. In our comments below, we suggest how we feel this could be addressed.
21	Royal College of Physicians.	General	We fully support the IBD Standards group response below: Population and topic to be covered – the draft quality standard refers to the topic overview which states that people with IBD-unspecified will not be covered. It is our strongly held view that the quality standard should apply to everyone with inflammatory bowel disease or suspected inflammatory bowel disease. It is confusing and unhelpful to exclude this group and makes no practical sense in terms of the specific quality statements and service delivery.
22	UK Clinical Pharmacy Association	General	These comments are in addition to the IBD Standards Group comments submitted by Jackie Glatter, Health Service Development Adviser, Crohn's and Colitis UK (Chair organisation for the IBD Standards Group)

ID	Stakeholder	Statement No	Comments[1]
23	UK Clinical Pharmacy Association	General	No additional comments
24	University Hospitals Birmingham	General	My comment is about the lack of consideration of anaemia management as a quality standard in this documentation. Anaemia and iron deficiency in particular is very common in IBD affecting up to 50% in patients and about 30% out-patients (70% children). This is the most common extra-intestinal manifestation of IBD and I feel strongly that prompt diagnosis and treatment of anaemia should be a quality standard in IBD.
25	Bladder & Bowel Foundation	Question 1	Yes
26	British Society of Paediatric and Adolescent Rheumatology	Question 1	The quality standards and introduction do not reflect the important concern of arthritis in children (or adults) with inflammatory bowel disease, the need to search for this in children with inflammatory bowel disease and importance of managing this effectively (to improve function eg school attendance and prevent long-term damage), usually in conjunction with a (Paediatric) Rheumatologist.
27	Ferring Pharmaceuticals	Question 1	We believe that patient adherence to an agreed therapy to be a key part of successful IBD treatment. In our internal market research, clinicians viewed it as the principle unmet need in the treatment of mild to moderate disease[6]. We would recommend emphasising its importance in Quality Statement 4.
28	Oxford University Hospitals NHS Trust	Question 1	The standards specifying that local pathways for referral, expert assessment, monitoring of drug of treatment, and regular follow-up are entirely appropriate, as is the standard that surgery should be in expert hands. Faecal calprotectin testing has now been available for many years, and better implementation is required. It would be appropriate for NICE to recommend that more research is supported in order to guide this development. There should be a section in the quality standard reflecting the need to appropriately monitor and treat known complications of IBD, including joint disease, poor nutrition, and anaemia. Iron deficiency anaemia affects over 15% of patients with IBD, and can have deleterious consequences including fatigue and cognitive dysfunction. It is therefore critically important that anaemia, and in particular iron deficiency is recognized and appropriately treated. This may require access to medications such as parenteral iron replacement therapy. Nutritional assessment particularly in paediatric patients and those with Crohn's disease affecting the small intestine should be considered as an independent quality standard. Psychological support especially for children and adolescents should be prioritized as a quality standard.

[6] Data on file

ID	Stakeholder	Statement No	Comments[1]
			Access to innovative treatments and clinical research should be considered as a quality standard, because it is widely recognized that the treatment of IBD remains unsatisfactory in some cases. Therefore patients who fail to respond to conventional therapy should be offered access to clinical studies and experimental therapies that might advance their own position, as well as the overall treatment of IBD in the UK. Prospective collection of data on IBD, including the BSG IBD registry, other local and national cohort databases, and registries that monitor the effects of treatment should be regarded as a quality standard that secondary care facilities treating IBD should support and implement
29	Bladder & Bowel Foundation	Question 2	Yes
30	British Society of Paediatric and Adolescent Rheumatology	Question 2	The quality standards seem very vague. With respect to arthritis I would suggest a standard that every child with inflammatory bowel disease has a documented pGALS assessment at diagnosis and annually. pGALS is a validated system which can be performed by all doctors (after initial brief training) to identify joint concerns, to trigger referral to a Paediatric Rheumatologist[5].
31	Ferring Pharmaceuticals	Question 2	No comment
32	Oxford University Hospitals NHS Trust	Question 2	It would be possible to collect data, although very difficult in practice, because systems are generally not in place. In particular, denominator data will be challenging, unless the quality standard includes explicit support for a registry.
33	Abbvie	Statement 1	Statement 1 only considers the referral of people with suspected IBD and does not address how a person should be categorised as suspected IBD rather than suffering from other gastrointestinal conditions. A key consideration should be to also consider how to improve the differential diagnosis of people with IBD symptoms in primary care to ensure that patients suspected of IBD are referred earlier.
34	Abbvie	Statement 1	We agree with the need for people with suspected IBD to be referred for specialist assessment. However, no indication is given to the importance of rapid referral. We believe this statement should give a time bound commitment for referral to avoid the risk of unplanned admissions due to IBD.
35	Abbvie	Statement 1	We suggest that minimum standards should be set for local referral pathways.
36	Bladder & Bowel Foundation	Statement 1	Should this contain a time period for the referral to be made within? (perhaps after a short period of monitoring)

ID	Stakeholder	Statement No	Comments[1]
37	British Society of Gastroenterology	Statement 1	Statement 1 is nebulous. The pathways referred to need to be aligned with the IBD Standards i.e. not just "local referral pathways". These pathways should adhere to the IBD standards / BSG standards. There is no reference to a timeframe for referral or timeframe between referral and diagnosis. Patients should ideally be referred to a unit which has good outcome data and which participates in the IBD audit or who send data to registries where they exist. Statement one could include the use of faecal calprotectin and therefore perhaps raise the profile of using faecal calprotectin in the GP community so that appropriate patients are referred.
38	British Society of Gastrointestinal and Abdominal Radiology	Statement 1	Referral for specialist assessment. The rationale mentions “a combination of haematological, endoscopic, histological and imaging-based investigations”. In terms of key areas for quality improvement there may be some advantage in looking at local access to MRI in the assessment of small bowel in Crohn’s disease. This technique avoids ionising radiation exposure (which can be cumulatively high in those serially investigated with x-ray based modalities such as fluoroscopy and CT) in younger people affected by the disease.
39	Crohn’s and Colitis UK	Statement 1	In order to avoid delays in diagnosis, it is necessary to ensure prompt identification of suspected IBD, efficient, potentially urgent referral and rapid access to diagnostic testing. This is of fundamental importance to people with inflammatory bowel disease who consistently report delays in diagnosis to us. We therefore welcome the recognition of this in the first quality statement, but believe it needs to be extended and strengthened to significantly improve the current situation. Patients with IBD have told us: *“The key to mitigating the effects of Inflammatory Bowel Disease is in getting a swift and accurate diagnosis in the first place. It took me 6 years of going to the IBD clinic time and time again... The devastation to my bowels was [then] revealed and the extent of the damage caused by the inflammation discovered.”* *“The diagnostic period can be lengthy and confusing for people with IBD, it's often not straight forward and can be traumatic at a time when you are very unwell. I feel that there needs to be something more defined in the standards about the diagnostic pathway, appreciating that the actual experience will be different for each individual.”* *“I have been referred by my GP as urgent to a GI doctor and I have waited 10 weeks for this appointment when I've had bleeding.”* *“I think general knowledge of IBD is poor-GPs and general doctors. I think there needs to be more focus on treating people based on their clinical condition ie symptoms, and less on blood results.”*

ID	Stakeholder	Statement No	Comments[1]
			"GP referral to a gastroenterologist changed the character and the quality of my treatment. Five previous GP referrals had been to the colorectal department at the hospital and were pretty fruitless and delayed the proper diagnosis of my condition." People often become ill after referral while they are waiting to be seen by a specialist, so referral pathways need to include time frames. There can also be delays in diagnostic testing. IBD Standard A4 states that possible IBD patients "should be contacted within two weeks of referral and seen within four weeks, or more rapidly if clinically necessary. Standard A9 defines time frames for endoscopic assessments and histological processing. All children under 16 should be referred to a paediatric gastroenterology service for initial investigation and treatment (Standard A12). Suggested wording: *People with suspected inflammatory bowel disease are referred to an appropriate multidisciplinary IBD service urgently for specialist assessment and investigation using agreed local referral pathways with defined timeframes for review, endoscopy and histology.* Alternatively, this could become two separate statements focusing on i) identification and r and ii) assessment..
40	Crohn's and Colitis UK	Statement 1	The rationale needs to refer to a specialist multidisciplinary team within an IBD service. Agreed local referral pathways with clearly defined timeframes for review and diagnostic testing should ensure rapid consultation and assessment.
41	Crohn's and Colitis UK	Statement 1	There is no definition of "specialist" or the essential role of the multidisciplinary team in IBD care. IBD Standards A1 and A2 define the IBD team and essential supporting services and these should be included within the definitions. The quality standard for rheumatoid arthritis follows this approach in outlining the rheumatology service and the supporting services required and would serve as a useful model. As outlined above, relevant timeframes from the IBD Standards can be included here, i.e.:

ID	Stakeholder	Statement No	Comments[1]
			• *People with suspected IBD should be contacted within two weeks of referral and seen within four weeks, or more rapidly if clinically necessary* • *There should be access to ultrasound/MRI/CT/contrast studies and endoscopic assessment within four weeks, maximum, or in more urgent situations, within 24 hours* • *Histological processing should be rapid (minimum standard five working days to report, but with arrangements to report urgent biopsy samples in two days when needed).*
42	Crohn's and Colitis UK	Statement 1	These [the measures] need to refer to the defined timeframes for referral, assessment and diagnostic testing given the current evidence of delay in these areas. For example, *the proportion of people with suspected inflammatory bowel disease seen in an IBD service within four weeks of referral*.
43	Dr Falk Pharma UK Ltd	Statement 1	Currently there are several primary care facilities with GPs with an interest in gastroenterology who carry out diagnosis including endoscopic assessments at their practices. This means that there is a growing number of IBD patients completely managed in primary care, not necessarily at a specialist hospital setting. This type of case should also be considered.
44	Dr Falk Pharma UK Ltd	Statement 1	The definition should include people with chronic non bloody diarrhoea i.e., those patients with microscopic colitis (collagenous colitis and lymphocytic colitis). There is a strong move at present to include microscopic colitis in the spectrum of inflammatory bowel diseases. This condition is grossly underdiagnosed, impacts greatly on patients quality of life and responds very well to certain anti-inflammatory agents such as topical steroids (budesonide). At present, pitfalls in the diagnostic workout occur at several levels 1. GPs not referring older female patients with chronic diarrhoea to endoscopy; 2. Endoscopists not taking serial biopsies from different anatomical segments of the colon; 3. Histopathologists not using the correct staining techniques.
45	Ferring Pharmaceuticals	Statement 1	We strongly support establishing robust local referral pathways. We would also highlight that to reach this standard of sensitivity in diagnosis there is a real need for those pathways to be efficient and to reduce the current high rates of unnecessary referrals. We would further highlight the role that point of care testing can play in this.
46	Gloucestershire Hospitals NHS Foundation Trust	Statement 1	This is an important point as it is recognised that many patients can wait several years after the onset of symptoms before a diagnosis is made. Most of this wait occurs in primary care and the emphasis on developing a pathway and GP education is supported. However, it would be helpful if the QS set clearer targets for timeliness of diagnosis and in particular introducing a 'referral to treatment target' would enable more objective audit of the standard. This would also help prioritise investigation of suspected cases.
47	IBD Standards Group	Statement 1	In order to avoid delays in diagnosis, it is necessary to ensure prompt identification of suspected IBD, efficient, potentially urgent referral and rapid access to diagnostic testing. We welcome the recognition of this in the first quality statement, but believe it needs to be extended and strengthened to achieve the desired results. People often become ill after referral while they are waiting to be seen by a specialist, so referral pathways need to include time frames. There can also be delays in diagnostic testing.

ID	Stakeholder	Statement No	Comments[1]
			IBD Standard A4 states that possible IBD patients "should be contacted within two weeks of referral and seen within four weeks, or more rapidly if clinically necessary. Standard A9 defines time frames for endoscopic assessments and histological processing. All children under 16 should be referred to a paediatric gastroenterology service for initial investigation and treatment (Standard A12). Suggested wording: *People with suspected inflammatory bowel disease are referred to an appropriate multidisciplinary IBD service urgently for specialist assessment and investigation using agreed local referral pathways with defined timeframes for review, endoscopy and histology.* Alternatively, this could become two separate statements focusing on i) identification and ii) assessment.
48	IBD Standards Group	Statement 1	The rationale needs to refer to a specialist multidisciplinary team within an IBD service. Agreed local referral pathways with clearly defined timeframes for review and diagnostic testing should ensure rapid consultation and assessment.
49	IBD Standards Group	Statement 1	There is no definition of "specialist" or the essential role of the multidisciplinary team in IBD care. IBD Standards A1 and A2 define the IBD team and essential supporting services and these should be included within the definitions. The quality standard for rheumatoid arthritis follows this approach in outlining the rheumatology service and the supporting services required and would serve as a useful model.
			As outlined above, relevant timeframes from the IBD Standards can be included here, i.e: People with suspected IBD should be contacted within two weeks of referral and seen within four weeks, or more rapidly if clinically necessary There should be access to ultrasound/MRI/CT/contrast studies and endoscopic assessment within four weeks, maximum, or in more urgent situations, within 24 hours

ID	Stakeholder	Statement No	Comments[1]
			Histological processing should be rapid (minimum standard five working days to report, but with arrangements to report urgent biopsy samples in two days when needed).
50	IBD Standards Group	Statement 1	These [the measures] need to refer to the defined timeframes for referral, assessment and diagnostic testing given the current evidence of delay in these areas. For example, *the proportion of people with suspected inflammatory bowel disease seen in an IBD service within four weeks of referral*.
51	Merck Sharp & Dohme	Statement 1	MSD supports the inclusion of this quality statement. However, we note that although the definition of 'Suspected inflammatory bowel disease' states that people with symptoms that have been present for at least 6 weeks should be suspected of having IBD and that people with more severe symptoms may need referral before 6 weeks, no time point has been included within the quality statement itself. We suggest amending the quality statement to: 'People with suspected inflammatory bowel disease are referred for specialist assessment and investigation using agreed local referral pathways within 6 weeks'. The time frame should also be incorporated into the quality measure for process i.e. the numerator should be amended to: 'the number in the denominator who receive specialist assessment and investigation within 6 weeks'. Although 6 weeks would be the preferred time point in order to align with the existing NICE guidance referenced here (DG11: Faecal calprotectin diagnostic tests for inflammatory diseases of the bowel), we understand that timelines for referral may need to vary according to local circumstances and therefore the quality statement and quality measure could be amended in such a way that allows for flexibility, i.e. 'People with suspected inflammatory bowel disease are referred for specialist assessment and investigation using agreed local referral pathways in a timely manner'.
52	Merck Sharp & Dohme	Statement 1	The quality measure for structure stipulates that there should be evidence of a local referral pathway but the supporting text in this quality statement does not specify the elements which these pathways should include. MSD suggests that the definition of the local referral pathway should be expanded to ensure that pathways can be designed to be fit for purpose. A numerator and denominator could be added to this quality measure, i.e. to determine the proportion of regions which have a referral pathway in place (with the denominator being the number of regions).

ID	Stakeholder	Statement No	Comments[1]
			MSD feels that the quality measure for process may not be stringent enough to drive improvements in clinical practice. The numerator and denominator calculate the proportion of people suspected of having IBD that are referred for specialist investigation and assessment. Ideally, this proportion would be 100% (otherwise it is not clear what is happening to these people after presenting with symptoms suggestive of IBD) – and therefore this metric could be interpreted as a binary indicator i.e. with 100% indicating optimum clinical practice and with less than 100% indicating that an improvement should be made. This may limit the usefulness of this quality measure. It may be more useful to apply this metric to the number of people being referred *within a specified timeline*, as more variation could be expected in this aspect of the process. Finally, the quality measure for outcome does not cover which aspects of patient experience will be measured or what constitutes a good patient experience. The addition of these details may improve clarity.
53	Royal College of Pathologists	Statement 1	"Inflammatory bowel disease includes Crohn's disease and ulcerative colitis (if it is not possible to diagnose one of these, a person may be described as having 'indeterminate colitis')." The term "indeterminate colitis" must be restricted to patients who have definite IBD in resection specimens which cannot be classified further as ulcerative colitis or Crohn's disease[7,8,9,10]. The term that is now recommended in every other circumstance is "inflammatory bowel disease, unclassified" or "IBDU"[10,11,12]. This is widely accepted in UK, European, and international guidelines. It is also important to note that there is no "third type" of IBD. The document sometimes implies the existence of a third type. Patients in the grey area usually have ulcerative colitis if they are eventually assigned to a category. Inappropriate use of the term "indeterminate colitis" by pathologists and clinicians has caused much confusion[7,10,11,13,14,15]. Indeed, many experts would prefer to see the term "indeterminate colitis" abandoned completely)[13].

[7] Stange EF, Travis SPL, Vermeire S, et al. for the European Crohn's and Colitis Organisation (ECCO). European evidence-based consensus on the diagnosis and management of ulcerative colitis: definitions and diagnosis. J Crohns Colitis 2008;2:1-23.
[8] Price AB. Overlap in the spectrum of non-specific inflammatory bowel disease - 'colitis indeterminate'. J Clin Pathol 1978;31:567-77.
[9] Yantiss RK, Sapp HL, Farraye FA, et al. Histologic predictors of pouchitis in patients with chronic ulcerative colitis. Am J Surg Pathol 2004;28:999-1006.
[10] Silverberg MS, Satsangi J, Ahmad T, et al. Toward an integrated clinical, molecular and serological classification of inflammatory bowel disease: Report of a Working Party of the 2005 Montreal World Congress of Gastroenterology. Can J Gastroenterol 2005;19 (Suppl A):5-36.
[11] Feakins RM. Inflammatory bowel disease biopsies: updated British Society of Gastroenterology reporting guidelines. J Clin Pathol 2013;66:1005-26.
[12] Mowat C, Cole A, Windsor A, et al. Guidelines for the management of inflammatory bowel disease in adults. Gut 2011;60:571-607.
[13] Geboes K, Colombel JF, Greenstein A, et al. Indeterminate colitis: a review of the concept--what's in a name? Inflamm Bowel Dis 2008;14:850-7.
[14] Hornick JL, Odze RD. Polyps of the large intestine. In: Odze RD, Goldblum JR, eds. Surgical pathology of the GI tract, liver, biliary tract and pancreas. 2nd edn. Philadelphia: Saunders Elsevier 2009:481-533.

ID	Stakeholder	Statement No	Comments[1]
			I would suggest replacing “indeterminate colitis” with “IBDU” wherever possible.
54	Royal College of Pathologists	Statement 1	“People with any of the following lower gastrointestinal symptoms that have been present for at least 6 weeks should be suspected of having inflammatory bowel disease: abdominal pain or discomfort, bloating, diarrhoea combined with rectal bleeding, or change in bowel habit [Adapted from NICE diagnostic guidance 11, section 3.1].” I am not sure why diarrhoea for 6 weeks (in the absence of rectal bleeding) is not sufficient for IBD to be considered; is it necessary to have both symptoms? Patients with Crohn’s disease in particular may present with diarrhoea and no blood15. However, I am not an expert in this specific area.
55	Royal College of Physicians.	Statement 1	Patients with suspected IBD should be referred urgently for further investigation. The inclusion of the standard ‘urgent’ timeline will aid diagnosis, support early treatment as an outpatient and may well avoid unscheduled admission. This should follow a similar structure to those already in place for the referral of people with suspected cancer. The adoption of the use of faecal calprotectin in primary care may facilitate appropriate referral. There is no definition of the term ‘specialist’ or the essential role of the multidisciplinary team in IBD care. IBD Standards A1 and A2 define the IBD team and essential supporting services and these should be included within the definitions. The quality standard for rheumatoid arthritis follows this approach in outlining the rheumatology service and the supporting services required and would serve as a useful model. IBD services should keep a local register of all patients with a diagnosis of IBD. We would suggest that the outcome measure be changed to: - The proportion of people seen in secondary care within 4 weeks of referral (IBD Standard A4)
56	UK Clinical Pharmacy Association	Statement 1	No additional comments
57	University of East Anglia	Statement 1	I am concerned at the apparent dismissal of GP involvement in IBD. Occasionally this may include endoscopy too. This important area of practice should not be neglected.
58	University of East	Statement 1	The definition is currently very restrictive and also wrong.

[15] Martland GT, Shepherd NA. Indeterminate colitis: definition, diagnosis, implications and a plea for nosological sanity. Histopathology 2007;50:83-96.

ID	Stakeholder	Statement No	Comments[1]
	Anglia		Indeterminate colitis is NOT what is described as this is a histological diagnosis only possible after colectomy for severe colitis. Additionally there is no space here for the various forms of microscopic colitis (most often collagenous or lymphocytic colitis but also eosinophilic). It is also to the disadvantage of patients with other types of colitis such as that caused by past radiotherapy or NSAIDs.
59	Vifor Pharma UK Ltd	Statement 1	Vifor Pharma welcome the inclusion of initial laboratory investigations as adapted from the British Society of Gastroenterology Guideline for the management of inflammatory bowel disease in adults. These investigations allow for the diagnosis of iron deficiency anaemia, the most common extra intestinal manifestation of inflammatory bowel disease. This can be a significant burden affecting the patient and diagnosis and appropriate management would help achieve Domain 2 of the NHS Outcomes Framework and Domain 1 of the Public health outcomes framework for England.
60	Abbvie	Statement 2	We are pleased to see NICE's strong recommendation in favour of person-centred care and suggest that it would be useful to emphasise the importance of supported self-management as a route to achieving this goal and empowering people with IBD. We believe that the comments regarding the importance of involving patients in discussion about their treatment are useful, but again it would be helpful if this point could be linked to the reason why this is important, namely patient choice and empowerment.
61	Abbvie	Statement 2	AbbVie welcomes the acknowledgement that people with IBD and their family members are supported to agree treatment options and monitoring arrangements but consider that this statement is defined too narrowly. We believe this measure should capture ensuring patients and family members or carers should be educated about IBD and empowered to engage in decision making about their care. This would include presenting the possible future disease journey as well as current treatment options. Patients should be able to help decide on treatments based on their personal treatment goals and their assessment of the risks and benefits of different treatment options, as well as their unique personal circumstances. All of this should be with the goal of delivering supported self-management as is common in other long term conditions.
62	Abbvie	Statement 2	Patients should have access to multi-disciplinary support at diagnosis and on an ongoing basis, *e.g*. dietetics, psychological support as appropriate. We recommend that this statement should highlight the importance of people with IBD having access to someone with whom they can discuss the impact of their condition on work (and/ or education, depending on their age) and how to manage this aspect of their care.
63	Abbvie	Statement 2	We propose amending the wording for this statement to clarify that this refers to paediatric treatment options versus adult treatment options. We are concerned that as currently worded this may lead to choice of treatment options in adults on account of age when lifestyle, treatment goals and risks of each treatment option would be more appropriate factors to consider than age alone.
64	Abbvie	Statement 2	The quality statements do not address what services should be in place for transitioning patients from paediatric to adult care. Access to appropriate transition arrangements should be in place.

ID	Stakeholder	Statement No	Comments[1]
65	Bladder & Bowel Foundation	Statement 2	This is a vital element of patient centred, coordinated care.
66	Bonpharma Ltd	Statement 2	Though comment is made regarding anaemia this would benefit from receiving greater stress. The iron deficiency and anaemia that patients may suffer can be a major contributor to their morbidity. A recent review by Stein and Dignas (*Annals of Gastroenterology* (2012) 26, 1-10) gives a figure of 16-74% of patients having anaemia with this varying between 16% in outpatients and 68% in hospitalized patients, 60-80% of patients are iron deficient. In view of these numbers specific mention of the importance of monitoring for iron deficiency and anaemia and subsequent management would be of benefit. Kulnigg and Gasche (2006) state that 21% of IBD patients (Aliment Pharmacol Ther 24, 1507–1523) may be intolerant to current high dose ferrous iron products to the degree that they discontinue treatment. When oral high dose ferrous products are either ineffective or not tolerated IV iron has been regarded as the next option. One alternative oral preparation currently undergoing trials is a combination of Heam and low dose ferrous iron which is showing encouraging results. A newer oral ferric iron product in development has been shown to be effective and tolerated in patients previously intolerant of currently approved oral high dose ferrous iron products (https://www.ecco-ibd.eu/publications/congress-abstract-s/abstracts-2014/item/dop079-correcting-iron-deficiency-anaemia-in-ibd-a-pivotal-phase-3-study-of-a-novel-oral-ferric-iron.html?highlight=YToxOntpOjA7czo0OiJzdDEwIjt9).
67	British Society of Gastroenterology	Statement 2	Statement 2 tries to encompass many aspects of care. It is very broad and there is a risk that the statement will become meaningless. There is a real danger of diluting aspects of care to a degree whereby the statement may become ineffective. Age appropriate treatment options need clarification. The statement could be improved by specifically stating the need for transitional care including psychological and emotional development. Perhaps “agree” could be changed to “decide”. The statement requires clarification; perhaps sub dividing into annual review, patient information and patient support. There is no mention of the importance of multidisciplinary discussion of patient care. It is commendable that the standard includes telephone support service and psychological support.
68	British Society of Gastrointestinal and Abdominal Radiology	Statement 2	Supporting person-centred care. Again, access to MRI may be an important marker of quality in terms of monitoring arrangements for Crohn’s disease. As above, this avoids ionising radiation exposure, particularly important in younger people and may provide better guidance regarding escalation of drug therapy or triage to surgery.
69	Crohn’s and Colitis UK	Statement 2	This statement, as currently drafted, covers several different important aspects of care which, in our view, need to be addressed separately. The key aspects covered are: patient information and support to enable decisions about treatment and effective self-management; ongoing monitoring/surveillance and age-appropriate care. We believe each of these aspects, all of which contribute significantly towards key quality of life outcomes indicators, are sufficiently diverse and important to warrant separate quality statements as outlined below.

ID	Stakeholder	Statement No	Comments[1]
			1. Patient information about the condition and its management in daily life, treatment options and support at all stages of an individual's illness are recognised as key priorities in the NICE guidelines. Information should be appropriate to the age, understanding and communication needs of the patient and carers. There is considerable evidence of variation in current practice. The UK IBD Audit includes questions about information provided to inpatients. Written care plans and support for self-management should be referred to in connection with this statement. Patient-reported outcome measures would clearly be very important here. *"My contact with my GP/consultant is 'groping in the dark' as I am not privy to or given the same information that is available to my doctors. This is in complete contrast to my experience in Greece... [where] next steps and monitoring and things for me to look out for are pointed out to me....[patients] need to be given copies of their test/biopsy/scan results so that the subsequent conversations that they have about their condition are informed."* *"Written information is important to support informed decisions."* *"Patients need to be given condition specific information from an accredited source, information about the IBD Service and how to access it as well as information about where else to find information and support. This enables a patient to self-manage effectively."*
			2. There is a need for ongoing monitoring and support of the individual's condition and its management and treatment over time to identify any need for a change in approach and ensure adequate surveillance for potential complications. This should include rapid access to specialist advice when needed. Rapid access to specialist input and early detection of relapse are referred to in the NICE guidelines for Crohn's Disease and Ulcerative Colitis. It is acknowledged that a large proportion of people with IBD are not under specialist care and are therefore not subject to appropriate long-term monitoring, e.g. for cancer. Patient portals can also be helpful in providing ongoing vigilance and ensuring rapid support when necessary. *"My care changed the day I met my IBD nurse...She goes a long way to make up for the deficiencies in the system."* *"Not all hospitals have specialist IBD nurses, we don't in our area"*

ID	Stakeholder	Statement No	Comments[1]
			"The actual experience will be different for each individual - at the very least this [pathways] need to reflect the vital need for clear information, communication, on-going support and psychological support too." *"I have been referred by my GP as urgent to a GI doctor and I have waited 10 weeks for this appointment when I've had bleeding, it's really not good enough."* *"As much as I have moved around the country, not one specialist offered me access to a dietician or counselling services since diagnosis in 2001."* *"[Value of care] under one roof - able to have multidisciplinary teams meet to discuss eg Crohn's management(gastro and surgical) + hepatitis management + pharmacy attend to advise appropriate drug therapy- also easier for the patient to attend one site and know case has been attended."* *"The use of patient portals can enable patients to self-manage and participate in their own care. We need to bear in mind though that some patients will still need or may have a preference for more directed care from their HP."*
			With regard to quality measures, IBD Standard A11 states that patients experiencing a possible relapse of their IBD should have access to specialist review within a maximum of five working days. Additionally, that all IBD patients who are not under immediate or ongoing care, including those in remission, should have an annual review and basic information recorded. All patients with confirmed IBD should have their details maintained on the register of IBD patients even when they are no longer regularly attending outpatient clinics to ensure appropriate monitoring and surveillance is taking place. 3. There is a growing incidence of paediatric IBD and an identified need for better recording of pubertal status and growth, targeted information and educational opportunities in relation to the condition and its management for children and adolescents, plans for transition to adult services and age-appropriate care. Given this, it is our view that a separate statement on age-appropriate care is required to encompass these elements. IBD Standard A12 defines arrangements for the care of children and young people who have IBD. Addressing age-appropriate care in a more specific way is likely to have a positive impact on outcome framework indicators such as attendance at school and children and young people's experience of outpatient services. Quality measures could focus on locally agreed policies for age-appropriate care and transition from paediatric to adult services.

ID	Stakeholder	Statement No	Comments[1]
			We welcome the descriptive section on *Monitoring arrangements* and *Responsible clinician* in relation to this statement, including reference to the multidisciplinary team, the need for colorectal cancer surveillance, renal function and bone densitometry, and growth and pubertal development in children and young people. We strongly support the statement in this section that *multidisciplinary support, including dietetic support, nursing support and psychological support should be available to all people with inflammatory bowel disease, and they should have access to a telephone service where they can raise concerns or questions*. We would just want to ensure it is clear that the dietetic support needs to be from a dietitian specialising in gastroenterology and that the nursing support is IBD specialist nurse input. Also that this is as part of the multidisciplinary team, at an appropriate level to ensure adequate cover at all times, with access to the defined essential supporting services (Standards A1 and A2). We also strongly welcome the descriptive text relating to reviews in this section. There is valuable additional information contained in the briefing paper in relation to patient information and support (E.g. NICE CG152 Recommendation 1.1.6 and NICE CG166 Recommendation 1.3.1, 1.3.2, 1.3.3, 1.3.4, 1.3.5), monitoring and surveillance and age-appropriate care. We suggest that some of this should also be included in the definitions sections for these statements.
70	Dr Falk Pharma UK Ltd	Statement 2	Although the majority of IBD patients are in primary care, the focus seems to be on the hospital based multidisciplinary team. There is a definite role for GPs in the long term care of these patients which should also be considered in greater detail further to the brief mentions on pages 13 and 19.
71	Ferring Pharmaceuticals	Statement 2	We strongly support the standard. We would like to highlight that different medication formulations and doses play a role in individualised patient care.
72	Gloucestershire Hospitals NHS Foundation Trust	Statement 2	This single standard appears to cover a wide range of issues and could perhaps be better split into 2 or 3 separate standards (it is noted that other QS documents often have more than 5 standards). The role of the IBD helpline, which we have provided in GHNHSFT for many years (albeit without specific funding) is welcome, as is the recommendation for psychological support for patients (currently not funded locally).
73	IBD Standards Group	Statement 2	This statement, as currently drafted, covers several different important aspects of care which, in our view, need to be addressed separately. The key aspects covered are: patient information and support to enable decisions about treatment and effective self-management; ongoing monitoring/surveillance and age-appropriate care. We believe each of these aspects, all of which contribute significantly towards key quality of life outcomes indicators, are sufficiently diverse and important to warrant separate quality statements as outlined below.

ID	Stakeholder	Statement No	Comments[1]
			1. Patient information about the condition and its management in daily life, treatment options and support at all stages of an individual's illness are recognised as key priorities in the NICE guidelines. Information should be appropriate to the age, understanding and communication needs of the patient and carers. There is considerable evidence of variation in current practice. The UK IBD Audit includes questions about information provided to inpatients. Written care plans and support for self-management should be referred to in connection with this statement. Patient-report outcome measures would clearly be very important here. 2. There is a need for ongoing monitoring and support of the individual's condition and its management and treatment over time to identify any need for a change in approach and ensure adequate surveillance for potential complications. This should include rapid access to specialist advice when needed. Rapid access to specialist input and early detection of relapse are referred to in the NICE guidelines for Crohn's Disease and Ulcerative Colitis. It is acknowledged that a large proportion of people with IBD are not under specialist care and are therefore not subject to appropriate long-term monitoring, e.g. for cancer.
			With regard to quality measures, IBD Standard A11 states that patients experiencing a possible relapse of their IBD should have access to specialist review within a maximum of five working days. Additionally, that all IBD patients who are not under immediate or ongoing care, including those in remission, should have an annual review and basic information recorded. All patients with confirmed IBD should have their details maintained on the register of IBD patients even when they are no longer regularly attending outpatient clinics to ensure appropriate monitoring and surveillance is taking place. Patient portals can also be helpful in providing ongoing vigilance and ensuring rapid support when necessary. 3. There is a growing incidence of paediatric IBD and an identified need for better recording of pubertal status and growth, targeted information and educational opportunities in relation to the condition and its management for children and adolescents, plans for transition to adult services and age-appropriate care. Given this, it is our view that a separate statement on age-appropriate care is required to encompass these elements. IBD Standard A12 defines arrangements for the care of children and young people who have IBD. Addressing age-appropriate care in a more specific way is likely to have a positive impact on outcome framework indicators such as attendance at school and children and young people's experience of outpatient services. Quality measures could focus on locally agreed policies for age-appropriate care and transition from paediatric to adult services.

ID	Stakeholder	Statement No	Comments[1]
			We welcome the descriptive section on *Monitoring arrangements* and *Responsible clinician* in relation to this statement, including reference to the multidisciplinary team, the need for colorectal cancer surveillance, renal function and bone densitometry, and growth and pubertal development in children and young people. We strongly support the statement in this section that *multidisciplinary support, including dietetic support, nursing support and psychological support should be available to all people with inflammatory bowel disease, and they should have access to a telephone service where they can raise concerns or questions*. We would just want to ensure it is clear that the dietetic support needs to be from a dietitian specialising in gastroenterology and that the nursing support is IBD specialist nurse input. Also that this is as part of the multidisciplinary team, at an appropriate level to ensure adequate cover at all times, with access to the defined essential supporting services (Standards A1 and A2). We also strongly welcome the descriptive text relating to reviews in this section. There is valuable additional information contained in the briefing paper in relation to patient information and support (E.g. NICE CG152 Recommendation 1.1.6 and NICE CG166 Recommendation 1.3.1, 1.3.2, 1.3.3, 1.3.4, 1.3.5), monitoring and surveillance and age-appropriate care. We suggest that some of this should also be included in the definitions sections for these statements.
74	Royal College of Physicians.	Statement 2	We fully support IBD standards group response as outlined below. We would however like to see the inclusion of the assessment and treatment of anaemia as a vital part of the monitoring of IBD (point 2). Most recent UK IBD audit data has demonstrated that 50% of IBD patients admitted to UK hospitals are anaemic and that this is sub-optimally treated (data are embargoed until 17 June 2014). We would also emphasise the comments made in point 3 below. Current UK IBD audit data have demonstrated that adolescent patients looked after in paediatric hospitals have a superior experience than those treated in adult hospitals. 73% of adolescents treated in a paediatric service rated their overall care as excellent compared to only 26% of adolescents treated in an adult service (data are embargoed until 17 June 2014). This statement as currently drafted, covers several different important aspects of care which in our view, need to be addressed separately. The key aspects covered are: patient information and support to enable decisions about treatment and effective self-management; ongoing monitoring/surveillance and age-appropriate care. We believe each of these aspects, all of which contribute significantly toward key quality of life outcomes indicators, are sufficiently diverse and important to warrant separate quality statements as outlined below.

ID	Stakeholder	Statement No	Comments[1]
			1. Patient information about the condition and its management in daily life, treatment options and support at all stages of an individual's illness are recognised as key priorities in the NICE guidelines. There is considerable evidence of variation in current practice. Written care plans and support for self-management should be referred to in connection with this statement. 2. There is a need for ongoing monitoring and support of the individual's condition and its management and treatment over time to identify any need for a change in approach and ensure adequate surveillance for potential complications. This should include rapid access to specialist advice when needed. Rapid access to specialist input and early detection of relapse are referred to in the NICE guidelines for Crohn's disease and ulcerative colitis. It is acknowledged that a large proportion of people with IBD are not under specialist care and are therefore not subject to appropriate long-term monitoring eg for cancer.
			IBD Standard A11 states that patients experiencing a possible relapse of their IBD should have access to specialist review within a maximum of five working days. Additionally, that all IBD patients who are not under immediate or ongoing care, including those in remission, should have an annual review and basic information recorded. All patients with confirmed IBD should have their details maintained on the register of IBD patients even when they are no longer regularly attending outpatient clinics to ensure appropriate monitoring and surveillance is taking place. Patient portals can also be helpful in providing ongoing vigilance and ensuring rapid support when necessary 3. There is a growing incidence of paediatric IBD and an identified need for better recording of pubertal status and growth, targeted information and educational opportunities in relation to the condition and its management for young people, plans for transition to adult services and age-appropriate care. Given this, it is our view that a separate statement on age-appropriate care is required to encompass these elements. IBD Standard A12 defines arrangements for the care of children and young people who have IBD. Addressing age-appropriate care in a more specific way is likely to have a positive impact on outcome framework indicators such as attendance at school and children and young people's experience of outpatient services. All patients aged $\leq$16 years with suspected IBD should be seen or discussed with paediatric GI services. We welcome the descriptive section on *Monitoring arrangements* and *Responsible clinician* in relation to this statement, including reference to the multidisciplinary team, the need for colorectal cancer surveillance, renal function and bone densitometry, and growth and pubertal development in children and young people. We strongly support the statement in this section that *multidisciplinary support, including dietetic support, IBD nursing support and psychological support should be available to all people with inflammatory bowel disease, and they should have access to a telephone service where they can raise concerns or questions*. We also strongly welcome the descriptive text

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			relating to reviews in this section. There is valuable additional information contained in the briefing paper in relation to patient information and support (E.g. NICE CG152 Recommendation 1.1.6 and NICE CG166 recommendations 1.3.1, to 1.3.5), monitoring and surveillance and age-appropriate care. We suggest that some of this should also be included in the definitions sections for these statements. Proposed outcome measures: - Proportion of patients provided with adequate information (patient–reported) - Proportion of IBD patients aged ≤16 looked after in an adult IBD service - Proportion of IBD patients with iron-deficiency anaemia, treated with iron. - Proportion of patients on a Thiopurine that have their bloods monitored at least 3 monthly
75	Royal Pharmaceutical Society	Statement 2	We support the use of a patient centred approach to ensure patients receive age-appropriate treatment options and appropriate monitoring arrangements. As experts in medicines, pharmacists provide advice on how to take medicines, adverse effects, possible interactions and cautions, to raise patients' and carers' awareness and increase their understanding of their condition and therapy and would therefore be ideally placed to form part of the multidisciplinary team that delivers this personalised approach to care and we suggest this is reflected in the standard.
76	UK Clinical Pharmacy Association	Statement 2	Additional comment|: we would like to see in the section 'Monitoring arrangements' the specialist pharmacist mentioned in the multidisciplinary team. An increasing number of units are using pharmacists to run drug monitoring clinics with the responsibility of prescribing the medication and the therapeutic drug monitoring (TDM services) of thiopurines and biologics. This is a developing field and pharmacists are well placed in taking this aspect of care over (see section 4) and manage drug therapies
77	University of East Anglia	Statement 2	We have good guidelines from national and international professional organisations. Those from the BSG are particularly relevant to British practice and together with the national audits are making a difference. It is unclear why NICE has decided to enter this arena. It is not the sort of thing NICE is good at. The guidance here seems very dogmatic about things that are better arranged at a local level and for which anyway

ID	Stakeholder	Statement No	Comments[1]
			the evidence base is poor. I would be happier to see these plans abandoned and for NICE to concentrate on what it does well.
78	Bladder & Bowel Foundation	Question 3	Yes, although more reference to the importance of a specialist nurse is required throughout the document. Specialist nurses often play a pivotal role in providing emotional support to this patient group. It would also be helpful to include a reference to raising awareness of patient groups which also provide valuable information, signposting and support.
79	British Society of Paediatric and Adolescent Rheumatology	Question 3	All patients and families should be educated about the risk of developing arthritis, gastroenterology teams should be proficient at performing pGALS screening examination and there should be pathways for referral to Paediatric Rheumatology departments when concerns.
80	Ferring Pharmaceuticals	Question 3	We would draw your attention to the varying patient support offered alongside the different therapies.
81	Oxford University Hospitals NHS Trust	Question 3	Specific mention should be made of nutritional assessment and support, identification and treatment of micronutrient deficiency, particularly iron deficiency, and of psychological support especially, although not exclusively, for children and adolescents.
82	Association of Coloproctocology of Great Britain and Ireland	Statement 3	Quality statement 3: Surgery Suggested amendment to Quality statement People with inflammatory bowel disease who need surgery have it undertaken by a colorectal surgeon, with a specialist interest in IBD, in a unit where the operations are performed frequently. Rationale The use of high-volume units where surgery for inflammatory bowel disease is performed frequently improves the likelihood of good outcome, because of the presence of experienced IBD surgeons, specialist nurses, access to specialist information and a pool of patients who are able to share experiences and offer mutual support. While high-volume units should be used for elective surgery, it may also be possible for people who are non-elective admissions to have surgery in high-volume IBD units when there is time for assessment and transfer after admission. Quality measures Structure Evidence of local arrangements to ensure that people with inflammatory bowel disease who have surgery have it undertaken by a colorectal surgeon, experienced in IBD surgery, in a unit where the operations are performed frequently. Data source: Local data collection. Process

ID	Stakeholder	Statement No	Comments[1]
			Proportion of people with inflammatory bowel disease who have surgery undertaken by a colorectal surgeon, experienced in IBD, in a unit where the operations are performed frequently. Numerator – the number in the denominator undertaken by a colorectal surgeon in a unit where the operations are performed regularly. Denominator – the number of elective procedures for inflammatory bowel disease. Data source: Local data collection and Hospital episode statistics from The Health and Social Care Information Centre. Quality standard for inflammatory bowel disease DRAFT (April 2014) p14 of 33 Outcome
			Complications after surgery. Data source: Local data collection. What the quality statement means for service providers, healthcare professionals and commissioners Service providers ensure that surgery for inflammatory bowel disease is undertaken by a colorectal surgeon, experienced in IBD surgery, in a unit where such operations are performed frequently. Healthcare professionals undertake surgery for inflammatory bowel disease in a unit where such operations are performed frequently, or refer people who may need surgery to colorectal surgeons in such units. Commissioners ensure that they commission services relating to surgery for inflammatory bowel disease from providers who can demonstrate that this surgery is undertaken in a unit where such operations are performed frequently by colorectal surgeons with experience in IBD surgery. What the quality statement means for patients, service users and carers People with inflammatory bowel disease who have surgery have their operation in a hospital where these types of operations are performed frequently, after full discussion of the benefits and risks. The operation should be carried out by a specialist surgeon called a colorectal surgeon with experience in IBD surgery. Source guidance • British Society of Gastroenterology (2011). Guidelines for the management of inflammatory bowel disease in adults, section 5.5 ‘Recommendations for surgery in ulcerative colitis’ and section 6.6.2 ‘Recommendations for surgery in Crohn’s disease’ (IBD service standards: A7)’. Quality standard for inflammatory bowel disease DRAFT (April 2014)

ID	Stakeholder	Statement No	Comments[1]
			Definitions of terms used in this quality statement Inflammatory bowel disease The two main forms of inflammatory bowel disease are Crohn's disease and ulcerative colitis. There may be some people whose inflammatory bowel disease is classed as 'indeterminate colitis' because it has not been possible to make a definitive diagnosis of either Crohn's disease or ulcerative colitis after full examination. This quality statement can also apply to people with indeterminate colitis [Adapted from British Society of Gastroenterology guideline, section 3.1]. Surgery The types of operation performed on people with inflammatory bowel disease include colectomy, ileo-anal pouch procedure, ileostomy and intestinal resection. [Adapted from NICE clinical guideline 152, NICE clinical guideline 166 and British Society of Gastroenterology guideline]
			Performed frequently Surgical units undertaking common conventional and laparoscopic IBD surgery frequently. For ileoanal pouch surgery units performing at least 10 cases (for example, ileo-anal pouch procedures) per year as a minimum. [British Society of Gastroenterology guideline, section 5.5] Surgeon with experience in IBD surgery Colorectal surgeons who represent a core member of an IBD MDT meeting and perform IBD surgery frequently.
83	Bladder & Bowel Foundation	Statement 3	Patients and their families need to have confidence in the team performing surgery.
84	British Society of Gastroenterology	Statement 3	This statement requires more detail. It could be improved by adding that the surgery should be undertaken by a colorectal surgeon *"who is experienced in inflammatory bowel disease surgery"*. Likewise it is suggested that there is an amendment such as "in a unit where operations are performed *frequently with multidisciplinary support and where outcome data are captured*". Perhaps greater detail could be included with reference to units performing e.g. 8 to 10 pouch operations per year. The unit should be one where 2 or more colorectal surgeons are present and are supported by at least 2 consultant gastroenterologists. There should also be access to a colorectal surgeon to perform emergency colectomies. The term indeterminate colitis should not be used, instead the term "IBD with a colonic phenotype" or "IBD unclassified" should be used.
85	Crohn's and Colitis UK	Statement 3	While we understand and support the basis of this statement, we believe that it needs to be more clearly defined and strengthened in order to have any positive impact on quality improvement.

ID	Stakeholder	Statement No	Comments[1]
			The colorectal surgeon should have specific IBD expertise and be a core member of the IBD team. We would suggest rewording “regularly” to “frequently” and defining this to apply to units with a higher volume of relevant surgery in which there are one or more colorectal surgeons with a special interest in IBD, supported by two physicians with an interest in IBD. It is important that the nature of surgeries performed, along with simple metrics on immediate and delayed complications and referral for medical follow up, should be formally recorded and audited. Pouch failure and salvage should be managed in a high-volume specialist unit. (IBD Standard A7).
			It is well-documented that auditing and the use of registries drives up quality and outcomes in surgical care and we therefore feel it is important to refer to these as part of this statement. IBD Standard E3 states that the outcomes of all emergency colectomy, ileoanal pouch and abdominal operations for Crohn’s Disease should be submitted to national audit and data collection.
86	Gloucestershire Hospitals NHS Foundation Trust	Statement 3	This is a helpful section, advocating the need for sub specialisation. However, the wording around recommended numbers of procedures could be tightened. What are ‘high volume units’?
87	IBD Standards Group	Statement 3	While we understand and support the basis of this statement, we believe that it needs to be more clearly defined and strengthened in order to have any positive impact on quality improvement. The colorectal surgeon should have specific IBD expertise and be a core member of the IBD team. We would suggest rewording “regularly” to “frequently” and defining this to apply to units with a higher volume of relevant surgery in which there are one or more colorectal surgeons with a special interest in IBD, supported by two physicians with an interest in IBD. It is important that the nature of surgeries performed, along with simple metrics on immediate and delayed complications and referral for medical follow up, should be formally recorded and audited. Pouch failure and salvage should be managed in a high-volume specialist unit. (IBD Standard A7). It is well-documented that auditing and the use of registries drives up quality and outcomes in surgical care and we therefore feel it is important to refer to these as part of this statement. IBD Standard E3 states that the outcomes of all emergency colectomy, ileoanal pouch and abdominal operations for Crohn’s Disease should be submitted to national audit and data collection.

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88	Merck Sharp & Dohme	Statement 3	'Performed regularly' is defined as surgical units undertaking at least 10 cases per year as a minimum. MSD understands that this definition is supported by BSG guidelines; however, we would like to understand how many centres where patients currently undergo surgery would actually be excluded according to this definition? If the number of required minimum cases was increased this may serve to better identify specialist centres in line with the aim of this quality statement.
89	The Royal College of Nursing	Statement 3	The list of quality statements (page 5) does not reference standards for timing- certainly statement 3- surgery, is a major problem in practice. Patients are waiting far too long for surgery impacting on their own and families lives and this statement does not appear to capture a standard or expectation on time for surgery which we consider an important feature as well as an experienced CR surgeon- perhaps a missed opportunity to have this as a quality measure? The term 'regular' is subjective and requires a definition.
90	Royal College of Pathologists	Statement 3	Should this include a line about the pre-operative histology being assessed by an expert histopathologist? This would follow the advice in the "IBD service standards" document and reproduced in the BSG clinical guidelines, as follows: "Recommendations for surgery [in Crohn's disease / ulcerative colitis] (IBD Service Standards: A7): Expert pathological assessment before surgery is important. This may involve referral to a recognised expert in the differential diagnosis of IBD[12,16].
91	Royal College of Pathologists	Statement 3	"Surgery The types of operation performed on people with inflammatory bowel disease include colectomy, ileo-anal pouch procedure, ileostomy and intestinal resection." I am not sure how "colectomy" differs from "intestinal resection". Does the latter perhaps refer to small intestinal resection? Please clarify this.
92	Royal College of Physicians.	Statement 3	We fully support the IBD standards response to this quality statement, as reiterated below:

[16] IBD Standards Group. Standards for the healthcare of people who have inflammatory bowel disease (IBD). 2013 update. Available from: http://www.ibdstandards.org.uk/uploaded_files/IBDstandards.pdf.

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			While we understand and support the basis of this statement, we believe that it is needs to be more clearly defined and strengthened in order to have any positive impact on quality improvement.
			The colorectal surgeon should have specific IBD expertise and be a core member of the IBD team. We would suggest rewording “regularly” to “frequently” and defining this to apply to units with a higher volume of relevant surgery in which there are one or more colorectal surgeons with a special interest in IBD, supported by two physicians with an interest in IBD. In paediatric services, surgery would be undertaken in conjunction with an experienced colorectal surgical unit. It is important that the nature of surgeries performed, along with simple metrics on immediate and delayed complications and referral for medical follow up, should be formally recorded and audited. Pouch failure and salvage should be managed in a high-volume specialist unit. (IBD Standard A7). It is well-documented that auditing and the use of registries drive up quality and outcomes in surgical care and we therefore feel it is important to refer to these as part of this statement. IBD Standard E3 states that the outcomes of all emergency colectomy, ileoanal pouch and abdominal operations for Crohn’s Disease should be submitted to national audit and data collection. Proposed outcome measure: - Proportion of patients with ‘good’ or ‘adequate’ results following pouch surgery (patient–reported)
93	UK Clinical Pharmacy Association	Statement 3	No additional comments
94	Abbvie	Statement 4	We support the proposed monitoring arrangements but believe these ought to go further. It would be helpful if all patients could have regular reviews and assessment of their disease severity regardless of whether they are treated with drugs, surgically, or with non-drug therapy. This should include a requirement to provide rapid access to a specialist in the event of a relapse

ID	Stakeholder	Statement No	Comments[1]
95	Abbvie	Statement 4	Data from the UK IBD audit indicates that routine monitoring of disease severity and quality of life using validated Patient Reported Outcomes Measures is not usually recorded even for patients requiring anti-TNF therapy[17]. Routine assessment including self-assessment using validated quality of life measures such as IBD-Control[18] and EQ-5D should be outlined so that in situations where a person's condition changes this can be effectively monitored and appropriate action taken. These reviews ought to be routine to ensure that treatment is altered as appropriate, reducing the need for acute care or surgery.
96	Bladder & Bowel Foundation	Statement 4	Regular reviews are an essential component of managing a long term condition.
97	British Society of Gastroenterology	Statement 4	This statement requires further detail. Currently it could be interpreted as any IBD patient who is started on medication should be monitored by someone. There should be clarification regarding who takes clinical responsibility for this monitoring i.e. agree appropriate monitoring arrangements. The statement seems to encompass efficacy of the treatments and not just drug monitoring. No mention is made of shared care guidelines between primary and secondary care. Neither is there any reference to allowing patients to self-manage. Many aspects of IBD services are carried out with discretionary support and there may need to be formal recognition / re negotiation of this type of care.
98	Crohn's and Colitis UK	Statement 4	This statement appears to be about ensuring optimal, safe and effective drug treatment. We feel this could be much clearer in the wording of the quality statement. We would suggest rewording along the following lines: *People with inflammatory bowel disease who are receiving drug treatment have the response to treatment actively monitored especially with regard to response to any new treatments for both efficacy and safety. Patients who are not responding or who experience significant side effects should be offered alternative treatment options..* Efficacy should be assessed at a timely interval, using objective measures of clinical disease activity together with biomarkers such as faecal calprotectin. The assessment of safety is also key to ensuring good outcomes for patients and should be a continual process.

[17] Biological therapies audit sub group. National clinical audit report of biological therapies. Adult national report. UK IBD audit. London: Royal College of Physicians. 2013.

[18] Bodger K, Ormerod C, Shackcloth D, Harrison M; on behalf of the IBD Control Collaborative. Development and validation of a rapid, generic measure of disease control from the patient's perspective: the IBD-Control questionnaire. Gut. 2013 Oct 9. doi: 10.1136/gutjnl-2013-305600.

ID	Stakeholder	Statement No	Comments[1]
			It would be helpful to refer to the role of shared care protocols between primary and secondary care for prescription of ongoing medication, monitoring of immunosuppressive drugs and monitoring of bone density or other parameters, as outlined in IBD Standard B. In addition to ensuring essential coordination over safety monitoring, this is also likely to improve people's experience of integrated care, a key outcomes framework indicator. The role of the specialist pharmacist is also important in this regard. *"Patient-centric integrated hospital, GP and community services are absolutely key"* It is important to ensure that people with inflammatory bowel disease are fully involved in monitoring treatment and listened to when they raise concerns. *"Side effects of treatments - should be listened to and acted on - having had Humira stop working and CRP hit 72; followed by infliximab induced hepatitis, sickness from azathioprine to lose most teeth and not been listened to."* Additionally, it should be recognised that compliance with medication can be helped or hindered by factors such as the method of taking the drug therapy and charges for prescription drugs, as well as side effects.
99	Crohn's and Colitis UK	Statement 4	The outcomes for patients receiving biological therapies should be submitted to the UK IBD biological therapies audit and the proportion of patients treated with a biologic and entered into the biological therapies audit a quality measure. The presence of shared care protocols would be another valuable quality measure.
100	Ferring Pharmaceuticals	Statement 4	Given the five-fold increase in relapse, in non-adherent patients[19], we suggest that adherence be monitored alongside response and that patient adherence be a consideration when weighing alternative treatment options.
101	Gloucestershire Hospitals NHS Foundation Trust	Statement 4	This seems to encompass the need for annual review as well as specific drug monitoring arrangements. However, the wording is very non-specific and seems unlikely to enhance care in its current form.

[19] Kane S, Huo D, Aikens J, Hanauer S. Medication non-adherence and the outcomes of patients with quiescent ulcerative colitis. Am J Med 2003; 114: 39–43.

ID	Stakeholder	Statement No	Comments[1]
102	IBD Standards Group	Statement 4	This statement appears to be about ensuring optimal, safe and effective drug treatment. We feel this could be much clearer in the wording of the quality statement. We would suggest rewording along the following lines: *People with inflammatory bowel disease who are receiving drug treatment have the response to treatment actively monitored for both efficacy and safety, especially with regard to response to any new treatments - patients who are not responding or who experience significant side effects should be offered alternative treatment options.* Efficacy should be assessed at a timely interval, using objective measures of clinical disease activity together with biomarkers such as faecal calprotectin. The assessment of safety is also key to ensuring good outcomes for patients and should be a continual process. It would be helpful to refer to the role of shared care protocols between primary and secondary care for prescription of ongoing medication, monitoring of immunosuppressive drugs and monitoring of bone density or other parameters, as outlined in IBD Standard B. In addition to ensuring essential coordination over safety monitoring, this is also likely to improve people's experience of integrated care, a key outcomes framework indicator. The role of the specialist pharmacist is also important in this regard.
103	IBD Standards Group	Statement 4	The outcomes for patients receiving biological therapies should be submitted to the UK IBD biological therapies audit and the proportion of patients treated with a biologic and entered into the biological therapies audit a quality measure. The presence of shared care protocols would be another valuable quality measure.
104	Merck Sharp & Dohme	Statement 4	MSD supports the inclusion of this quality statement. However, no timeframe for the monitoring arrangements ('regular check-ups') is specified within the quality statement. At the Topic Engagement meeting, 12 months was discussed as a potential timeframe for monitoring arrangements; however, MSD feels that 12 months is too infrequent and that 6 months would be more appropriate, with the caveat that the timeframe may be dependent on the therapy received (in-line with ECCO guidelines). For instance, people receiving corticosteroids may require more frequent monitoring due to the potential for adverse events and people receiving treatment with biologics may require monitoring at the end of the induction period (then transitioning to 6-monthly assessments throughout the maintenance period).

ID	Stakeholder	Statement No	Comments[1]
			MSD suggests that existing service provisions (i.e. those that deliver medicines and patient support via a homecare arrangement) could provide an appropriate framework through which to ensure patients are monitored in a timely manner.
105	The Royal College of Nursing	Statement 4	Drug treatment (page 17) the wording "other treatment options if needed" is unclear - there are other options available sometimes but organisations are not able to use these due to problems around NICE authorisation etc. Patients may read the QS and then be upset that "other options" cannot be offered in practice. Maybe the addition of a phrase such as "where available" or "NICE approved" should be added?
106	Royal College of Physicians.	Statement 4	The monitoring of drug treatment comprises two essential aspects, namely the assessment of efficacy and of safety. Efficacy should be assessed at a timely interval, using objective measures of clinical disease activity together with biomarkers such as faecal calprotectin. Patients who do not have adequate efficacy should have their treatment stopped. The assessment of safety is also key to ensuring good outcomes for patients. This should be a continual process addressed at every interaction between clinician and patient. Patients on relatively safe medicines should have this addressed as part of the annual review, those on more toxic medicines will need more frequent monitoring ideally as part of a local shared-care protocol. The role of the specialist pharmacist is also important in this regard. The outcomes for patients receiving biological therapies should be submitted to the UK IBD biological therapies audit. Proposed outcome measures: - Proportion of patients treated with a biologic and entered into the biological therapies audit
107	UK Clinical Pharmacy Association	Statement 4	See additional comment in section 2. The place of TDM of IBD therapies is still in development and the impact on treatment decisions yet to be fully determined, but it is clear that this aspect of monitoring will increase in the near future and the input of specialist pharmacists are going to be essential in managing this complex area of treatment.
108	Abbvie	statement 5	We welcome the emphasis on the provision of faecal calprotectin testing but consider that there should also be a time period specified for referral of patients to a gastroenterologist where clinical symptoms and faecal calprotectin indicate a high risk of IBD.
109	Bladder & Bowel Foundation	Statement 5	Again a time period for the referral to be made within may be helpful.
110	British Society of Gastroenterology	Statement 5	Faecal calprotectin is important but perhaps it does not deserve it's own specific statement. If it was included within statement 1 (i.e. within locally agreed pathways) there would be room for more statements. Thus statement 2 would not have to encompass so many aspects of patient care.

ID	Stakeholder	Statement No	Comments[1]
111	Crohn's and Colitis UK	Statement 5	We support the use of faecal calprotectin to aid decision making on appropriate referral of people with suspected IBD in primary care. We would welcome the inclusion of the use of faecal calprotectin as an adjunct to the clinical assessment of symptoms and response to treatment. Symptoms in Crohn's Disease are a poor indicator of the level of underlying mucosal inflammation. It is likely that disease complications are at least in part driven by this sub-clinical mucosal inflammation. For those over 50, colorectal cancer is more common and faecal calprotectin is of less value in this group. *"It would be good if there was earlier testing e.g. if GPs could request faecal calprotein tests this would show whether there was inflammation in the bowel and may result in quicker referral to gastro team at hospital. There is often long wait at the start of the process."* *"I get told because my bloods are normal it's all psychosomatic- even though I'm on immunosuppressants."*
112	Dr Falk Pharma UK Ltd	Statement 5	The faecal calprotectin test may not pick up patients with microscopic colitis, so these patients may be mistakenly identified with irritable bowel syndrome and delayed further testing and diagnosis. This scenario should be covered.
113	Ferring Pharmaceuticals	Statement 5	We strongly support this standard. We would suggest making it explicit that the standard is for Calprotectin use in primary care, before referral to specialist assessment. Given the recommendation for calprotectin use by both NICE and the BSG and the relative ease with which calprotectin can be implemented in a diagnostic pathway, we would suggest this standard not be viewed as developmental but as a full Quality Statement.
114	Gloucestershire Hospitals NHS Foundation Trust	statement 5	This seems out of place as its own standard and would be better incorporated into the referral pathways advocated under QS 1. Furthermore, the evidence base for calprotectin use in IBD is now well established and I do not understand the need to consider this as a developmental standard.
115	IBD Standards Group	Statement 5	We support the use of faecal calprotectin to aid decision making on appropriate referral of people with suspected IBD in primary care. We would welcome the inclusion of the use of faecal calprotectin as an adjunct to the clinical assessment of symptoms and response to treatment (Standard A4). Symptoms in Crohn's Disease are a poor indicator of the level of underlying mucosal inflammation. It is likely that disease complications are at least in part driven by this sub-clinical mucosal inflammation. For those over 50, colorectal cancer is more common and faecal calprotectin is of less value in this group.

ID	Stakeholder	Statement No	Comments[1]
116	Merck Sharp & Dohme	Statement 5	MSD supports the uptake of new diagnostic techniques that allow people to be diagnosed and appropriately treated at the earliest opportunity. However, we disagree that the faecal calprotectin test represents the 'cutting edge of practice' and therefore this quality statement should not be a developmental statement. We believe that this quality statement represents a valuable opportunity to drive the routine use of this diagnostic tool as part of best clinical practice, particularly as NICE guidance for the technology already exists (DG11: Faecal calprotectin diagnostic tests for inflammatory diseases of the bowel). This quality statement may link with quality statement 1; the diagnostic tool may contribute to the identification of and referral of patients for specialist assessment, and could be used to support the timely referral of patients.
117	Royal College of Paediatrics and Child Health	Statement 4	Opinions on the role of faecal calprotection for the diagnosis of IBD in children vary significantly. A raise faecal calprotection level can have serious causes. It should be in combination with other tests. More research is needed.
118	Royal College of Physicians.	Statement 5	We support the use of faecal calprotectin to aid decision making on appropriate referral of patients with suspected IBD in primary care. We would also echo the comments that in patients over the age of 50, colorectal cancer is more common and faecal calprotectin is of less value in this group. Symptoms in Crohn's disease are a poor indicator of the level of underlying mucosal inflammation. It is likely that disease complications are at least in part driven by this sub-clinical mucosal inflammation. We would welcome the inclusion of the use of faecal calprotectin as an adjunct to the clinical assessment of symptoms and response to treatment. Proposed outcome measures: - Proportion of patients referred with suspected IBD who have had faecal calprotectin measured
119	UK Clinical Pharmacy Association	Statement 5	No additional comment
120	University of East Anglia	Statement 5	The faecal calprotectin test is both strongly advocated in some parts and said to have been inadequately evaluated in others. This sends exactly the opposite message from what NICE ought to stand for. Again it is dealt with well by the BSG. Let us not have a surfeit of guidelines.

ID	Stakeholder	Statement No	Comments[1]
121	Bladder & Bowel Foundation	Question 4	Yes
122	Ferring Pharmaceuticals	Question 4	We believe that calprotectin testing is relatively straight forward to implement into a care pathway and when used at point of care, does not require significant changes. There are a significant number of prepared care pathways including calprotectin testing. While calprotectin testing in primary care is currently rare, it is becoming increasing common in secondary care. Our experience working with CCGs and local practices has highlighted a need for change in coordinating the funding of diagnostic pathways between primary and secondary care. We believe that calprotectin has the potential to be widely adopted, improving referral efficiency. Point of care testing in primary care is seen as something that adds value, can enhance outcomes, minimises inconvenience for patients and reduces inappropriate referrals. Experience is being gained in Secondary Care which can be used to support Pathway development.
123	Oxford University Hospitals NHS Trust	Question 4	Faecal calprotectin testing remains developmental and relatively under-used because it remains suboptimal. The need to collect and process fecal samples is a barrier, the wide range of normal values and disagreement about appropriate thresholds remains a problem. Therefore further research is needed. It is not so reliable a test that it can be used exclusively to determine access to specialized tests such colonoscopy. For instance, it may underestimate the chance of patients have Microscopic colitis, or of having Crohn's disease in some cases.

Stakeholders who submitted comments at consultation

- Abbvie
- Association of Coloproctocology of Great Britain and Ireland
- Bladder & Bowel Foundation
- Bonpharma Ltd
- British Infection Association
- British Society of Gastroenterology

- British Society of Gastrointestinal and Abdominal Radiology
- British Society of Paediatric and Adolescent Rheumatology
- Crohn’s and Colitis UK
- Department of Health
- Digital assessment service, NHS Choices
- Dr Falk Pharma UK Ltd
- Ferring Pharmaceuticals
- Gloucestershire Hospitals NHS Foundation Trust
- IBD Standards Group
- Merck Sharp & Dohme
- NHS England
- Nutricia Advanced Medical Nutrition
- Oxford University Hospitals NHS Trust
- The Royal College of Nursing
- Royal College of Pathologists
- Royal College of Physicians
- Royal Pharmaceutical Society
- UK Clinical Pharmacy Association
- University Hospitals Birmingham
- University of East Anglia

- Vifor Pharma UK Ltd