NATIONAL INSTITUTE FOR HEALTH AND   
CARE EXCELLENCE

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION

SUMMARY REPORT

1. Quality standard title

Irritable bowel syndrome in adults.

Date of Quality Standards Advisory Committee post-consultation meeting:   
29 October 2015

1. Introduction

The draft quality standard for irritable bowel syndrome in adults was made available on the NICE website for a 4-week public consultation period between 28 August and 25 September 2015. 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 9 organisations, which included 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.

1. 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?

3. Do you have an example from practice of implementing the NICE guideline that underpins this quality standard? If so, please submit your example to the NICE local practice collection [here](https://www.nice.org.uk/about/what-we-do/into-practice/local-practice-case-studies/submit-a-case-study-example). Examples of using NICE quality standards can also be submitted.

1. General comments

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

* Stakeholders generally agreed that the quality standard reflects key areas for improvement.
* Three stakeholders felt there should be more explicit reference to the need to test for coeliac disease before diagnosing IBS (see notes under statement 2, page 5).

### Consultation comments on data collection

* A stakeholder commented that it would be possible to collect the data for the proposed quality measures using the [clinical practice research datalink](http://www.cprd.com/intro.asp) (please note this is a sample research database and is unlikely to be a good source of local measurement of achievement against the quality standard).

1. Summary of consultation feedback by draft statement
   1. Draft statement 1

Adults with suspected irritable bowel syndrome are offered tests for inflammatory markers to exclude inflammatory causes.

### Consultation comments

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

* A stakeholder stated that a normal CRP alone does not rule out inflammatory bowel disease and this should be stated in the quality standard as faecal calprotectin testing is not universally available to GPs.
* A stakeholder noted that some new markers such as faecal S100A12 are not mentioned in the statement though the evidence base is still building.
  1. Draft statement 2

Adults are given a diagnosis of irritable bowel syndrome if no red flag indicators are present and investigations identify no other cause of symptoms.

### Consultation comments

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

* A stakeholder encouraged the diagnosis of IBS if no red flag indicators are present and identifications identify no other cause.
* It was suggested that the 6 month timescale in the guideline is added to the statement.
* A stakeholder noted that the guideline does not list family history of coeliac disease as a red flag symptom however the quality standard does. They felt the inclusion is correct and the guideline should reflect this for consistency.
* Although coeliac disease is listed in definitions underpinning this quality statement as one of the other causes of symptoms to be considered before IBS is diagnosed, several stakeholders suggested that ruling out coeliac disease is important enough to merit more explicit reference – potentially as an additional statement similar to statement 1 which refers to excluding inflammatory causes.
  1. Draft statement 3

Adults with irritable bowel syndrome who still have symptoms after following general lifestyle and dietary advice, are offered advice on single food avoidance and exclusion diets.

### Consultation comments

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

* A stakeholder felt the statement is too vague to be useful to GPs and may confuse patients.
* A query was raised over how long the general advice should be followed and a suggestion was made to reword the statement: Adults with IBS are offered advice on single food avoidance and exclusion diets only after following general lifestyle and dietary advice for at least……
* A stakeholder commented that there is no specific mention of GPs with a specialist interest in IBS who may be able to provide this advice.
* A stakeholder commented that elements of the definition of general lifestyle and dietary advice lack evidence or no longer apply, however FODMAP is evidence-based therefore they felt this should be part of first line general dietary advice.
* A stakeholder felt local systems for referrals to healthcare practitioners with expertise in dietary management or specialist dietitians may not be in place.
* A stakeholder stated that single food avoidance applies only to allergies which are rare in adults with IBS.
* A stakeholder commented that low FODMAP is a restricted, not exclusion diet, which most people can follow with apps or fact sheets to manage symptoms.
* A stakeholder felt that a low FODMAP diet could be given with psychological treatments and/or probiotics to reduce visceral sensitivity.
* A stakeholder commented that people can find reintroducing FODMAPs to their diet difficult and may need assistance from a specialist dietitian.
  1. Draft statement 4

Adults with irritable bowel syndrome have a review of treatment and management at least once a year.

### Consultation comments

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

* A stakeholder commented that many people manage continuing symptoms themselves. Annual review should be restricted to those for whom there is an evidence base that review improves outcomes.
* It was suggested that the 12 month review is not necessary for everyone with IBS and a suggestion was made to change the focus of the statement to a specific group of patients.

1. Suggestions for additional statements

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

* Three stakeholders felt it is important to exclude coeliac disease as a cause of symptoms (see notes under statement 2).
* It was noted that there are no statements on medication. A stakeholder identified a reluctance of GPs to prescribe or review newly licensed medication such as Linaclotide and others such as tricyclic antidepressants therefore they suggested including a statement on timely prescribing in line with symptoms, not just once a year.
* A stakeholder noted that the quality standard does not state when people should be referred to secondary care.

# Appendix 1: Quality standard consultation comments table – registered stakeholders

| **ID** | **Stakeholder** | **Statement number** | **Comments[[1]](#footnote-1)** |
| --- | --- | --- | --- |
| 1 | UK Clinical Pharmacy Association (UKCPA) | General | I agree with the list of quality statements. |
| 2 | Royal College of General Practitioners | Consultation question 1 | Yes, this draft quality standard does accurately reflect the key areas for quality improvement, but the focus is on exclusion of inflammatory bowel disease only and not other pathology, including coeliac disease. |
| 3 | Royal College of General Practitioners | Consultation question 2 | Yes, it would be possible to collect the data for the proposed quality measures, using the Clinical Practice Research Database (CPRD). |
| 4 | Royal College of General Practitioners | Consultation question 3 | No, I do not have any. |
| 5 | British Medical Association | Statement 1 | There is great emphasis on using faecal calprotectin and CRP to exclude inflammatory causes of symptoms, and thus avoid invasive procedures such as colonoscopies and sigmoidoscopies. However, it should be stressed, that a normal CRP alone does not rule out inflammatory bowel disease, and we believe this should be included in the quality statement especially as faecal calprotectin is not universally available to GPs, |
| 6 | British Medical Association | Statement 1 | Some of the new markers such as faecal S100A12 are not discussed in the quality statement. However, it should be noted that the evidence base is still building up. |
| 7 | British Medical Association | Statement 2 | The diagnosis of IBS if no red flag indicators are present and investigations identify no other cause of their symptoms is encouraged. |
| 8 | British Specialist Nutrition Association | Statement 2 | BSNA have noted that the list of ‘red flags’ differs between the published clinical guidance on ‘Irritable bowel syndrome in adults: diagnosis and management if irritable bowel syndrome in primary care’ (CG61), and the draft quality standard. In the guidance document (CG61) there is no mention of ‘family history of coeliac disease’ as a symptom which requires referral to secondary care. We believe that it is an important ‘red flag’ and are in agreement that it is listed in the quality standard. However, BSNA believe there should be consistency between the clinical guidance and the quality standard. |
| 9 | British Specialist Nutrition Association | Statement 2 | The British Specialist Nutrition Association (BSNA) represents manufacturers of products designed to meet specialist nutritional needs including infant products such as infant or follow-on formula, complementary weaning foods, parenteral nutrition and medical foods for diagnosed disorders and medical conditions, gluten-free foods and sports foods. The BSNA helps its members operate in a highly-regulated environment to support the competitive landscape and communicate the industry's knowledge, values and concerns to Government, regulators, healthcare professionals and the media.  The BSNA welcomes the consultation and opportunity to comment on the NICE Quality Standard on Irritable Bowel Syndrome (IBS). We fully support the identification of 'making a diagnosis' as a key area for quality improvement as covered in 'Statement 2. Adults are given a diagnosis of irritable bowel syndrome if no red flag indicators are present and investigations identify no other cause of symptoms.' However, in view of the current NICE IBS Guideline recommendation to exclude coeliac disease prior to making a diagnosis of IBS, and the established evidence base supporting the relationship between these two conditions, we would urge consideration to be given to making Statement 2 more explicit in relation to the exclusion of a diagnosis of coeliac disease. |
| 10 | Coeliac UK | Statement 2 | The symptoms of irritable bowel syndrome (IBS) are similar to both inflammatory bowel disease and coeliac disease. Research shows that 1 in 4 people with coeliac disease have previously received treatment for irritable bowel syndrome [1], therefore it is likely that coeliac disease is often misdiagnosed as IBS. Statement 1 should state “Adults with suspected irritable bowel syndrome are offered tests for inflammatory markers and coeliac disease to exclude these causes” to reduce the likelihood of a misdiagnosis with IBS. This would better reflect previous and updated NICE guidelines for irritable bowel syndrome and coeliac disease [2, 3] which recommend offering serological testing for coeliac disease to people with irritable bowel syndrome.  [1] Card TR, Siffledeen J, West J et al (2013) An excess of prior irritable bowel syndrome diagnoses or treatments in Celiac disease: evidence of diagnostic delay. Scand J Gastroenterol 48(7): 801–7. doi: 10.3109/00365521.2013.786130  [2] Coeliac disease: recognition, assessment and management (2015) NICE guideline NG20, recommendation 1.1.1  [3] Irritable bowel syndrome in adults: diagnosis and management of irritable bowel syndrome in primary care (2008) NICE guideline CG61 recommendation 1.1..2.1 |
| 11 | Coeliac UK | Statement 2 | Before an exclusion diet or a low FODMAP diet is initiated, the patient should be serologically tested for coeliac disease. This is because serological testing for coeliac disease is only accurate if a gluten-containing diet is eaten during the diagnostic process and is in line with current NICE recommendations [1].  [1] Coeliac disease: recognition, assessment and management (2015) NICE guideline NG20, recommendation 1.1.3 |
| 12 | Royal College of General Practitioners | Statement 2 | Yes, this draft quality standard does accurately reflect the key areas for quality improvement, but the focus is on exclusion of inflammatory bowel disease only and not other pathology, including coelaic disease. In NICE guidelines on Coeliac disease ([http://www.nice.org.uk/guidance/ng20/chapter/1-Recommendations#referral-of-people-with-suspected-coeliac-disease](http://www.nice.org.uk/guidance/ng20/chapter/1-Recommendations%20-%20referral-of-people-with-suspected-coeliac-diseasehttp:/www.nice.org.uk/guidance/ng20/chapter/1-Recommendations%23referral-of-people-with-suspected-coeliac-disease) SNGD 20 September 2015) serological testing for coeliac disease is recommended for gastrointestinal symptoms that are similar to irritable bowel disease.  I would ask consideration to widen the initial investigations to:   * Full blood count * C Reactive Protein * Serological testing for Coeliac disease * Urea and electrolytes * Liver function testing   Faecal calprotectin |
| 13 | The IBS Network | Statement 3 | Adults with irritable bowel syndrome who still have symptoms after following general lifestyle and dietary advice, are offered advice on single food avoidance and exclusion diets.  I feel this statement too vague to be useful guide for GPs and may lead to confusion among patients.  It is not generally agreed what comprises general lifestyle and dietary advice and many of the qualifiers on the list lack evidence or no longer apply.  Evidence does however exist for the short term benefits of reducing poorly absorbed, small molecular weight carbohydrates (FODMAPs) on symptoms of bloating and diarrhoea. My personal view is that this should be included as part of general (first line) dietary advice.  Single food avoidance only applies to allergies (Lactose is a FODMAP), which are rare in adults with IBS.  The low FODMAP diet is a restricted diet, not an exclusion diet. With appropriate fact sheets or apps, most patients can manage to restrict FODMAPs sufficiently to calm their symptoms.  A low FODMAP diet is not for life, but some patients find reintroduction of FODMAPs difficult and may need the assistance of specialist dietitians.  Intestinal sensitivity is increased in many patients with IBS and may render them sensitive to FODMAPs. Hence a low FODMAP diet could usefully be given alongside psychological treatments and or probiotics to reduce visceral sensitivity |
| 14 | British Medical Association | Statement 3 | The quality statement promotes for adults with IBS, who still have symptoms after following general lifestyle and dietary advice, to be referred to a healthcare practitioner with expertise in dietary management or to a specialist dietitian if necessary. However, not all localities have such systems in place. Additionally, there is no specific mention of GPs with a specialist interest in IBS who may be able to provide this service, though it should not be expected that this is a normal part of GP services. |
| 15 | British Medical Association | Statement 4 | It is recommended that adults with IBS have a review of treatment or management at least once a year, either during a face-to-face appointment or a telephone consultation. However, IBS is very common and many patients manage continuing symptoms themselves. This self-care is to be encouraged and routine annual review should be restricted to groups for whom there is an evidence base that review improves outcomes. In the absence of such evidence review is likely to encourage medicalisation of symptoms and increase the likelihood of the taking on of a sickness-role, to the detriment of the patient’s overall health. |
| 16 | UK Clinical Pharmacy Association (UKCPA) | Additional area | I agree with the list of quality statements. However, one of the problems we are having locally is that GPs within primary care are reluctant to prescribe and review newly licensed medication such as Linaclotide and others such as TCAs.  In light of the above an additional statement should be added to state that timely prescribing and review of medication should take place in line with the patient’s symptoms and not just once a year.  As per NICE clinical guideline 61- IBS in adults diagnosis and management of IBS in primary care.  GPs can start Linaclotide and are asked to follow patients up within 3 months. However, locally we are following the SPC and asking GPs to give a trial of 4weeks then review, also asking GPs to do the 4 week review if started in secondary care.  After speaking to a few GPs their main apprehension around prescribing is down to lack of understanding of the condition and of new drugs – hence training, teaching and support (pathways) from secondary are needed. |
| 17 | UK Clinical Pharmacy Association (UKCPA) | Additional area | The document does not state at what point patients should be referred to secondary care – some patients we see at our trust as outpatients can be managed in primary care with the use of local pathways. |
| 18 | BSPGHAN | N/A | We wish to express our views to this guideline which we believe does not fit for children and young people in this form. If NICE aims to apply this guideline to children and young people, it will be essential to involve a paediatric gastroenterologist to the review team.  We would think it would be ideal to have a separate paediatric guideline for IBS in children and young people.  In the initial briefing paper <http://www.nice.org.uk/guidance/gid-qsd118/resources/irritable-bowel-syndrome-in-adults-qs-briefing-paper2> it states in the overview pg 2.1  **"Focus of quality standard**  **This quality standard will cover the diagnosis and management of irritable bowel syndrome (IBS) in children, young people and adults. "**  The briefing paper then, however, contains minimal information regarding children and young people. The only input seems to come from input from the BDA (BSPGHAN is listed as a stakeholder).  **However, actual quality standard paper that is open for consultation ONLY REFERS TO ADULTS i.e.**  (1) title: **Irritable bowel syndrome in adults**,  NICE quality standard, Draft for consultation  (2) the words “child”, “children” and “young” does not appear in it at all apart from 1 (one) reference to another published NICE quality standard i.e. Constipation in children and young people (2014) NICE quality standard 62  (3) there are no paediatricians/child related professionals in the specialist committee  (4) the word ‘adult’ appears 94 times in the consultation and child once  (5) that standard questions are entirely based on adult data and documents such as previous NICE documents on IBS in Adults  (5) although there will be overlap between IBS in children and adults there are areas that will not be relevant related to symptoms, work, alcohol intake, risk of cancers such as ovarian etc  Overall, we are concerned that the quality standard open to consultation is specifically relevant only to adults but it gives the impression that this applies to children and young people – which clearly it does not. There is no reference to children at all nor an implication that they would be seen by adult providers.  Is there another paper being produced that is specifically relevant to this age group? If so, we wish to express our strong view that a member of BSPGHAN, ideally from the motility working group, should eb aprt of the paediatric-specific guideline. |
| 19 | UK Clinical Pharmacy Association (UKCPA) | N/A | (Page 5 training and competencies ) In order to avoid discrepancies between different area(s) / sites a nationally or centrally accessible resource should be created and made available |
| 20 | NHS England | N/A | Thank you for the opportunity to comment on the above Quality Standard. I wish to confirm that NHS England has no substantive comments to make regarding this consultation. |
| 21 | Department of Health | N/A | Thank you for the opportunity to comment on the draft for the above quality standard.  I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation. |

## Registered stakeholders who submitted comments at consultation

* British Medical Association
* British Society of Paediatric Gastroenterology, Hepatology and Nutrition
* British Specialist Nutrition Association
* Coeliac UK
* Department of Health
* NHS England
* Royal College of General Practitioners
* The IBS Network
* UK Clinical Pharmacy Association

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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. [↑](#footnote-ref-1)