



## General

### Guideline Title

Irritable bowel syndrome in adults: diagnosis and management of irritable bowel syndrome in primary care.

### Bibliographic Source(s)

National Collaborating Centre for Nursing and Supportive Care. Irritable bowel syndrome in adults: diagnosis and management of irritable bowel syndrome in primary care. London (UK): National Institute for Health and Care Excellence (NICE); 2015 Feb. 37 p. (Clinical guideline; no. 61).

### Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: National Collaborating Centre for Nursing and Supportive Care. Irritable bowel syndrome in adults. Diagnosis and management of irritable bowel syndrome in primary care. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Feb. 27 p. (Clinical guideline; no. 61).

This guideline meets NGC's 2013 (revised) inclusion criteria.

## Recommendations

### Major Recommendations

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Collaborating Centre for Nursing and Supportive Care (NCC-NSC) on behalf of the National Institute for Health and Care Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

The following guidance is based on the best available evidence. The full guideline gives details of the methods and the evidence used to develop the 2008 recommendations. The guideline addendum (see the "Availability of Companion Documents" field) gives details of the methods and the evidence used to develop the 2015 recommendations.

Recommendations are marked as [new 2015], [2015] and [2008]:

- [new 2015] indicates that the evidence has been reviewed and the recommendation has been added or updated
- [2015] indicates that the evidence has been reviewed but no change has been made to the recommendation action
- [2008] indicates that the evidence has not been reviewed since 2008.

### Diagnosis of Irritable Bowel Syndrome (IBS)

Confirming a diagnosis of IBS is a crucial part of this guideline. The primary aim should be to establish the person's symptom profile, with

abdominal pain or discomfort being a key symptom. It is also necessary to establish the quantity and quality of the pain or discomfort, and to identify its site (which can be anywhere in the abdomen) and whether this varies. This distinguishes IBS from cancer-related pain, which typically has a fixed site.

When establishing bowel habit, showing people the Bristol Stool Form Scale (see Appendix I in the full version of the guideline) may help them with description, particularly when determining quality and quantity of stool. People presenting with IBS symptoms commonly report incomplete evacuation/rectal hypersensitivity, as well as urgency, which is increased in diarrhoea-predominant IBS. About 20% of people experiencing faecal incontinence disclose their incontinence only if asked. People who present with symptoms of IBS should be asked open questions to establish the presence of such symptoms (for example, 'tell me about how your symptoms affect aspects of your daily life, such as leaving the house'). Healthcare professionals should be sensitive to the cultural, ethnic and communication needs of people for whom English is not a first language or who may have cognitive and/or behavioural problems or disabilities. These factors should be taken into consideration to facilitate effective consultation.

### Initial Assessment

Healthcare professionals should consider assessment for IBS if the person reports having had any of the following symptoms for at least 6 months:

- Abdominal pain or discomfort
- Bloating
- Change in bowel habit [2008]

All people presenting with possible IBS symptoms should be asked if they have any of the following 'red flag' indicators and should be referred to secondary care for further investigation if any are present (see the NICE [Referral guidelines for suspected cancer](#)  (NICE clinical guideline 27), for detailed referral criteria where cancer is suspected):

- Unintentional and unexplained weight loss
- Rectal bleeding
- A family history of bowel or ovarian cancer
- A change in bowel habit to looser and/or more frequent stools persisting for more than 6 weeks in a person aged over 60 years [2008]

All people presenting with possible IBS symptoms should be assessed and clinically examined for the following 'red flag' indicators and should be referred to secondary care for further investigation if any are present (see the NICE [Referral guidelines for suspected cancer](#)  (NICE clinical guideline 27), for detailed referral criteria where cancer is suspected):

- Anaemia
- Abdominal masses
- Rectal masses
- Inflammatory markers for inflammatory bowel disease [2008]

Measure serum CA125 in primary care in women with symptoms that suggest ovarian cancer in line with the NICE guideline of ovarian cancer. [2008] Note: This recommendation was updated in September 2012 in line with more recent guidance on the recognition and management of ovarian cancer in the NGC summary of the NICE guideline [Ovarian cancer. The recognition and initial management of ovarian cancer](#) (NICE clinical guideline 122).

A diagnosis of IBS should be considered only if the person has abdominal pain or discomfort that is either relieved by defaecation or associated with altered bowel frequency or stool form. This should be accompanied by at least two of the following four symptoms:

- Altered stool passage (straining, urgency, incomplete evacuation)
- Abdominal bloating (more common in women than men), distension, tension or hardness
- Symptoms made worse by eating
- Passage of mucus

Other features such as lethargy, nausea, backache and bladder symptoms are common in people with IBS, and may be used to support the diagnosis. [2008]

### Diagnostic Tests

In people who meet the IBS diagnostic criteria, the following tests should be undertaken to exclude other diagnoses:

- Full blood count (FBC)

- Erythrocyte sedimentation rate (ESR) or plasma viscosity
- C-reactive protein (CRP)
- Antibody testing for coeliac disease (endomysial antibodies [EMA] or tissue transglutaminase [TTG]) [2008]

The following tests are not necessary to confirm diagnosis in people who meet the IBS diagnostic criteria:

- Ultrasound
- Rigid/flexible sigmoidoscopy
- Colonoscopy; barium enema
- Thyroid function test
- Faecal ova and parasite test
- Faecal occult blood
- Hydrogen breath test (for lactose intolerance and bacterial overgrowth) [2008]

### Clinical Management of IBS

#### Dietary and Lifestyle Advice

People with IBS should be given information that explains the importance of self-help in effectively managing their IBS. This should include information on general lifestyle, physical activity, diet and symptom-targeted medication. [2008]

Healthcare professionals should encourage people with IBS to identify and make the most of their available leisure time and to create relaxation time. [2008]

Healthcare professionals should assess the physical activity levels of people with IBS, ideally using the General Practice Physical Activity Questionnaire (GPPAQ) (see Appendix J in the full guideline appendices [see the "Availability of Companion Documents" field]). People with low activity levels should be given brief advice and counselling to encourage them to increase their activity levels.

Diet and nutrition should be assessed for people with IBS and the following general advice given.

- Have regular meals and take time to eat.
- Avoid missing meals or leaving long gaps between eating.
- Drink at least eight cups of fluid per day, especially water or other non-caffeinated drinks, for example herbal teas.
- Restrict tea and coffee to 3 cups per day.
- Reduce intake of alcohol and fizzy drinks.
- It may be helpful to limit intake of high-fibre food (such as wholemeal or high-fibre flour and breads, cereals high in bran, and whole grains such as brown rice).
- Reduce intake of 'resistant starch' (starch that resists digestion in the small intestine and reaches the colon intact), which is often found in processed or re-cooked foods.
- Limit fresh fruit to 3 portions per day (a portion should be approximately 80 g).
- People with diarrhoea should avoid sorbitol, an artificial sweetener found in sugar-free sweets (including chewing gum) and drinks, and in some diabetic and slimming products.
- People with wind and bloating may find it helpful to eat oats (such as oat-based breakfast cereal or porridge) and linseeds (up to one tablespoon per day). [2008]

Healthcare professionals should review the fibre intake of people with IBS, adjusting (usually reducing) it while monitoring the effect on symptoms. People with IBS should be discouraged from eating insoluble fibre (for example, bran). If an increase in dietary fibre is advised, it should be soluble fibre such as ispaghula powder or foods high in soluble fibre (for example, oats). [2008]

People with IBS who choose to try probiotics should be advised to take the product for at least 4 weeks while monitoring the effect. Probiotics should be taken at the dose recommended by the manufacturer. [2008]

Healthcare professionals should discourage the use of aloe vera in the treatment of IBS. [2008]

If a person's IBS symptoms persist while following general lifestyle and dietary advice, offer advice on further dietary management. Such advice should:

- Include single food avoidance and exclusion diets (for example, a low FODMAP [fermentable oligosaccharides, disaccharides, monosaccharides and polyols] diet).

- Only be given by a healthcare professional with expertise in dietary management. [new 2015]

## Pharmacological Therapy

Decisions about pharmacological management should be based on the nature and severity of symptoms. The recommendations made below assume that the choice of single or combination medication is determined by the predominant symptom(s).

Healthcare professionals should consider prescribing antispasmodic agents for people with IBS. These should be taken as required, alongside dietary and lifestyle advice. [2008]

Laxatives should be considered for the treatment of constipation in people with IBS, but people should be discouraged from taking lactulose. [2008]

Consider linaclotide for people with IBS only if:

- Optimal or maximum tolerated doses of previous laxatives from different classes have not helped and
- They have had constipation for at least 12 months.

Follow up people taking linaclotide after 3 months. [new 2015]

Loperamide should be the first choice of antimotility agent for diarrhoea in people with IBS. [2008]

People with IBS should be advised how to adjust their doses of laxative or antimotility agent according to the clinical response. The dose should be titrated according to stool consistency, with the aim of achieving a soft, well-formed stool (corresponding to Bristol Stool Form Scale type 4). [2008]

Consider tricyclic antidepressants (TCAs) as second-line treatment for people with IBS if laxatives, loperamide or antispasmodics have not helped. Start treatment at a low dose (5–10 mg equivalent of amitriptyline), taken once at night, and review regularly. Increase the dose if needed, but not usually beyond 30 mg.\* [2015]

Consider selective serotonin reuptake inhibitors (SSRIs) for people with IBS only if TCAs are ineffective.\* [2015]

Take into account the possible side effects when offering TCAs or SSRIs to people with IBS. Follow up people taking either of these drugs for the first time at low doses for the treatment of pain or discomfort in IBS after 4 weeks and then every 6–12 months.\* [2015]

\* At the time of publication (February 2015), TCAs and SSRIs did not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the [General Medical Council's Good practice in prescribing and managing medicines and devices](#)  for further information.

## Psychological Interventions

Referral for psychological interventions (cognitive behavioural therapy [CBT], hypnotherapy and/or psychological therapy) should be considered for people with IBS who do not respond to pharmacological treatments after 12 months and who develop a continuing symptom profile (described as refractory IBS). [2008]

## Complementary and Alternative Medicine (CAM)

The use of acupuncture should not be encouraged for the treatment of IBS. [2008]

The use of reflexology should not be encouraged for the treatment of IBS. [2008]

## Follow-Up

Follow-up should be agreed between the healthcare professional and the person with IBS, based on the response of the person's symptoms to interventions. This should form part of the annual patient review. The emergence of any 'red flag' symptoms during management and follow-up should prompt further investigation and/or referral to secondary care. [2008]

## Definitions:

### Strength of Recommendations

Some recommendations can be made with more certainty than others. The Committee makes a recommendation based on the trade-off between the benefits and harms of an intervention, taking into account the quality of the underpinning evidence. For some interventions, the Committee is confident that, given the information it has looked at, most patients would choose the intervention. The wording used in the recommendations in this

guideline denotes the certainty with which the recommendation is made (the strength of the recommendation).

#### *Interventions That Must (or Must Not) Be Used*

The Guideline Development Group (GDG) usually uses 'must' or 'must not' only if there is a legal duty to apply the recommendation. Occasionally the GDG will use 'must' (or 'must not') if the consequences of not following the recommendation could be extremely serious or potentially life threatening.

#### *Interventions That Should (or Should Not) Be Used – a 'Strong' Recommendation*

The GDG uses 'offer' (and similar words such as 'refer' or 'advise') when confident that, for the vast majority of patients, an intervention will do more good than harm, and be cost effective. The GDG uses similar forms of words (for example, 'Do not offer...') when the GDG is confident that an intervention will not be of benefit for most patients.

#### *Interventions That Could Be Used*

The GDG uses 'consider' when confident that an intervention will do more good than harm for most patients, and be cost effective, but other options may be similarly cost effective. The choice of intervention, and whether or not to have the intervention at all, is more likely to depend on the patient's values and preferences than for a strong recommendation, and so the healthcare professional should spend more time considering and discussing the options with the patient.

#### *Recommendation Wording in Guideline Updates*

NICE began using this approach to denote the strength of recommendations in guidelines that started development after publication of the 2009 version of 'The guidelines manual' (January 2009). This does not apply to any recommendations ending [2008] (see 'Update information' above for details about how recommendations are labelled). In particular, for recommendations labelled [2008] the word 'consider' may not necessarily be used to denote the strength of the recommendation.

## Clinical Algorithm(s)

An algorithm titled "IBS Algorithm" is provided in the full version of the guideline (see the "Availability of Companion Documents" field).

A National Institute for Health and Care Excellence (NICE) care pathway titled "Irritable Bowel Syndrome in Adults Overview" is available from the [NICE Web site](#) .

## Scope

### Disease/Condition(s)

Irritable bowel syndrome (IBS)

### Guideline Category

Diagnosis

Evaluation

Management

Treatment

### Clinical Specialty

Family Practice

Gastroenterology

Internal Medicine

Psychology

## Intended Users

Advanced Practice Nurses

Dietitians

Nurses

Patients

Physicians

Psychologists/Non-physician Behavioral Health Clinicians

## Guideline Objective(s)

- To provide positive diagnostic criteria for people presenting with symptoms suggestive of irritable bowel syndrome (IBS)
- To provide guidance on clinical and cost-effective management of IBS in primary care
- To determine clinical indications for referral to IBS services, taking into account cost-effectiveness

## Target Population

Adults (18 years and older) who present to primary care with symptoms suggestive of irritable bowel syndrome (IBS)

Note: This guideline does not cover:

People with other gastrointestinal disorders such as non-ulcer dyspepsia or coeliac disease  
Children and young people under 18 years  
Inflammatory bowel disease

## Interventions and Practices Considered

Diagnosis/Evaluation

1. Initial assessment
  - Evaluation of symptoms
  - Physical examination, including examination for "red flag" indicators
  - Referral to secondary care
2. Diagnostic tests
  - Full blood count (FBC)
  - Erythrocyte sedimentation rate (ESR) or plasma viscosity
  - C-reactive protein (CRP)
  - Antibody testing for coeliac disease (endomysial antibodies [EMA] or tissue transglutaminase [TTG])

Note: The following tests were considered but not recommended to confirm diagnosis: ultrasound, rigid/flexible sigmoidoscopy, colonoscopy, barium enema, thyroid function test, faecal ova and parasite test, faecal occult blood test, hydrogen breath test.

Management/Treatment

1. Dietary and lifestyle advice
2. Pharmacological therapy
  - Antispasmodic agents

- Laxatives
  - Linaclotide (only if indicated)
  - Loperamide
  - Tricyclic antidepressants (TCAs) (second-line treatment)
  - Selective serotonin reuptake inhibitors (SSRIs) (only if TCAs are ineffective)
3. Referral for psychological interventions
    - Cognitive behavioural therapy (CBT)
    - Hypnotherapy
    - Psychological therapy
  4. Complementary and alternative medicine (CAM), including acupuncture and reflexology (not recommended)
  5. Follow-up

## Major Outcomes Considered

- Symptomatic improvement
- Quality of life
- Adverse effects
- Cost-effectiveness of diagnostic tests and management interventions

## Methodology

### Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Searches of Electronic Databases

### Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Collaborating Centre for Nursing and Supportive Care (NCC-NSC) on behalf of the National Institute for Health and Care Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

#### 2008 Guideline

Clinical Effectiveness Review Methods

#### *Search Strategy*

The search strategies and the databases searched are presented in detail in Appendix B in the full guideline appendices (see "Availability of Companion Documents" field). All searches were carried out on the following core databases: Medline, EMBASE, CINAHL (all using the OVID interface) and The Cochrane Library. Additional databases were searched for individual reviews where appropriate.

For this guideline, a general set of terms was produced relating to irritable bowel syndrome (IBS). The relevance of the terms diarrhoea and constipation was explored before they were included in the IBS filter. For each review, terms related to the intervention were combined with the set of IBS terms. Where appropriate, study design filters (randomised controlled trial [RCT] and systematic review) were applied. Results were limited to papers published in English where possible. All searches were updated to June 2007.

Hand-searching was not undertaken following NICE advice that exhaustive searching on every guideline review topic is not practical or efficient. Reference lists of articles were checked for studies of potential relevance.

#### *Methods of the Review*

#### Sifting Process

Once the search had been completed, the following sifting process took place:

- 1st sift: one reviewer sifted the title/abstract for articles that potentially met the eligibility criteria
- 2nd sift: full papers were ordered that appeared relevant and eligible or where relevance/eligibility was not clear from the abstract
- 3rd sift: full papers were appraised, generally by one reviewer using an inclusion criteria form, and this was checked where necessary by a second reviewer.

### Quality Assessment and Validity

Once individual papers were retrieved, the articles were checked for methodological rigour (using quality checklists appropriate for each study design), applicability to the United Kingdom (UK) and clinical significance. Assessment of study quality concentrated on dimensions of internal validity and external validity. At this stage, some studies were excluded if the interventions were not licensed for use in the UK or they were not regularly used in the UK. Studies in which the interventions were obsolete were also excluded.

Studies for which the methodological quality indicated a high potential for bias were included in the review, but were not included in the analysis.

### Cost-effectiveness Review Methods

#### *Objectives of Cost-effectiveness Review*

1. To determine the cost-effectiveness of tests to identify alternative diagnoses in patients meeting the diagnostic criteria for IBS who do not have any 'red-flag' symptoms.
2. To assess the cost-effectiveness of interventions used in the management of IBS.

#### *Search Strategy for Identification of Studies*

Searches were performed on the Medline database for objective 1 using the strategy given in Appendix B in the full guideline appendices. Specific searches were also performed on the National Health Service Economic Evaluation Database (NHS EED) database using the medical subject heading (MeSH) terms for inflammatory bowel disease (exploded to include Crohn's disease and ulcerative colitis), lactose intolerance and coeliac disease. Free-text searching on the NHS EED database was explored but did not yield any further relevant papers.

Searches were performed on the Medline database for objective 2 using the strategy in Appendix B in the full guideline appendices. Specific searches were also performed on the NHS EED database using the MeSH term for irritable bowel syndrome which yielded two further papers. Free-text searching on the NHS EED database was explored but did not yield any further relevant papers.

### 2015 Update

See Appendix D in the Addendum to NICE Guideline CG61, Irritable Bowel Syndrome in Adults (see the "Availability of Companion Documents" field) for the clinical and health economic search summaries for each review question.

## Number of Source Documents

2011 Guideline

Not stated

2015 Update

See Appendix E in the Addendum to NICE Guideline CG61, Irritable Bowel Syndrome in Adults (see the "Availability of Companion Documents" field) for the number of studies included for each review question.

## Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Weighting According to a Rating Scheme (Scheme Given)

## Rating Scheme for the Strength of the Evidence



## Grading Evidence

For some reviews, the Guideline Development Group used the GRADE (Grading of Recommendations Assessment, Development and Evaluation) scheme to assess the quality of the evidence for each outcome using the approach described below, and evidence summaries across all outcomes were produced.

According to the GRADE scheme, evidence is classified as high, moderate, low or very low:

- High - further research is very unlikely to change the confidence in the estimate of effect
- Moderate - further research is likely to have an important impact on the confidence in the estimate of effect and may change the estimate
- Low - further research is very likely to have an important impact on the confidence in the estimate of effect and is likely to change the estimate
- Very low - any estimate of effect is very uncertain

The procedure adopted when using GRADE was:

1. A quality rating was assigned, based on the study design – for example, randomised controlled trials (RCTs) started as high and observational studies as low.
2. This rating was up or downgraded according to specified criteria: study quality, consistency, directness, preciseness and reporting bias. These criteria are detailed in the full version of the guideline (see the "Availability of Companion Documents" field). Criteria were given a downgrade mark of -1 or -2 depending on the severity of the limitations.
3. The downgrade/upgrade marks were then summed and the quality rating revised. For example, a decrease of -2 points for an RCT would result in a rating of 'low'.
4. Wherever possible, reasoning was explained for the downgrade marks.

## Methods Used to Analyze the Evidence

Meta-Analysis of Randomized Controlled Trials

Systematic Review with Evidence Tables

## Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Collaborating Centre for Nursing and Supportive Care (NCC-NSC) on behalf of the National Institute for Health and Care Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

### 2008 Guideline

#### Data Abstraction

Data from the included studies were extracted by one reviewer for each review, with random checking by a second reviewer, and entered into a Microsoft Access relational database that had been especially designed for the guideline. The use of the database provided a more structured extraction, for example, only certain choices could be made for some items, although free text fields were also used. The main advantage of using a database for this purpose is that a large amount of detail can be input, and then an overview obtained using database sorting procedures. The following data were extracted from each study:

- Review being addressed
- Study details: study design (randomised controlled trial [RCT], quasi-randomised, cohort study, etc.); parallel/crossover, washout period; country where trial conducted; setting; funding
- Study quality
- Participants: age (mean and range), gender (ratio male:female), co-morbidities, inclusion/exclusion criteria, irritable bowel syndrome (IBS) diagnosis method, type of IBS, presence of bloating, presence of pain, measure of severity of IBS, symptom status at trial entry, length of time since diagnosis, duration of symptoms, ethnicity, socio-economic group, weight, post-infective/non post-infective initiated IBS
- Interventions: class (e.g., insoluble fibre) and sub-class (e.g., wheat bran), total amount per day, frequency/time of consumption, means of delivery (oral capsule, taken as a food, drink, etc.), duration of treatment; concurrent treatment in both arms
- Comparator: placebo (details of what it is), other control group, other intervention

- Outcome: including follow-up period, scales used, definition of success (if using 'improved', 'complete response', etc.)
- Results for each outcome

### Appraisal of Methodological Quality

The methodological quality of each trial was assessed by one reviewer and randomly checked by a second. See Section 5.2 in the full version of the guideline for a list of quality items that were assessed.

### Data Synthesis

Meta-analysis of similar trials, where appropriate, was carried out using The Cochrane Collaboration's analysis software, Review Manager (Version 4.2). Trials were pooled using a fixed effects model and plotted on forest plots. Where there was significant heterogeneity, a random effects model was used as a sensitivity analysis.

For dichotomous studies, reviewers used the analyses reported by the authors, which was usually those reporting an outcome. Where there were incomplete data reported (more than 20% missing in any one group), reviewers carried out sensitivity analyses, excluding these studies.

Where it was possible to combine studies, outcomes were summarised for dichotomous data using odds ratios (as default), relative risks (where the event rate in either arm was greater than 20%), or Peto odds ratios (where there were studies with no events in one arm). Numbers needed to treat (with the control group rate to which they apply) were calculated from the risk difference, where appropriate. The number needed to treat (NNT) is the number of people who would have to be treated for one to have an improved outcome.

Refer to Section 5.2 in the full version of the guideline for additional information.

### 2015 Update

See Appendix H in the Addendum to NICE Guideline CG61, Irritable Bowel Syndrome in Adults (See the "Availability of Companion Documents" field) for the GRADE profiles for each review question.

## Methods Used to Formulate the Recommendations

### Expert Consensus

Expert Consensus (Nominal Group Technique)

## Description of Methods Used to Formulate the Recommendations

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### 2008 Guideline

#### Formulating Recommendations and Determining Key Recommendations

##### *Evidence to Recommendations*

Each review summarises the evidence, and the Guideline Development Group (GDG) is asked to interpret the evidence before drafting recommendations. In each case, this includes a consideration of the clinical and cost effectiveness evidence; an indication of the factors the GDG took into account, including the balance between benefits and harms; the GDG's reasoning and conclusions, and, where relevant, the level of agreement amongst the group. This is reported in each individual review section of the full version of the guideline, illustrating the relationship between published clinical and cost effective evidence and recommendations for clinical practice.

##### *Key Recommendations*

### Process

The GDG was asked to vote on key recommendations by secret email ballot using an Excel spreadsheet. This incorporated the full list of recommendations and votes were allocated to the group, in order to try and determine the key priorities for the guideline. Developing consensus

through validated instruments is key to ensure that the final list of up to ten key recommendations fully reflect the group as a whole. This enables all constituent members of the group to have equal weighting of opinion as their opinion moves towards a consensus group position. Typically, nominal group technique (NGT) works well for small groups, with 12 to 15 people widely acknowledged in the literature as the maximum number of people involved in this process.

See Section 5.5 in the full version of the guideline to see the results of voting.

### Summary

The NGT worked well in developing consensus opinion, reflected by the key recommendations emergent from the process. The nine key recommendations represent the heart of the full guideline and full guideline recommendations. They articulate the evidence supporting the key areas of healthcare practice that will be shaped by the guideline, providing the possibility with effective implementation for people with irritable bowel syndrome (IBS) symptoms being properly diagnosed and managed within primary care.

### 2015 Update

See the [Interim process and methods guide for updates pilot programme 2013](#)  and the [Guidelines manual 2012](#)  (see also the "Availability of Companion Documents" field).

NICE's Clinical Guidelines Update Programme updated this guideline in 2015. This guideline was updated using a Committee of healthcare professionals, methodologists and lay members from a range of disciplines and localities, as well as topic experts.

## Rating Scheme for the Strength of the Recommendations

### 2008 Guideline

Not applicable

### 2015 Update

#### Strength of Recommendations

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#### *Recommendation Wording in Guideline Updates*

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details about how recommendations are labelled). In particular, for recommendations labelled [2008] the word 'consider' may not necessarily be used to denote the strength of the recommendation.

## Cost Analysis

### 2008 Guideline

#### Cost-effectiveness Review Methods

Whilst cost-effectiveness is an important consideration for all recommendations made within the guideline, two areas were identified as being priority areas for which cost-effectiveness evidence would have particular importance for informing recommendations. These were identified by the health economist in conjunction with the Guideline Development Group (GDG) after consideration of the importance of each clinical question in terms of the number of patients likely to be affected and the impact on costs and health outcomes for those patients.

The use of tests to exclude alternative diagnoses in people with irritable bowel syndrome (IBS)-like symptoms was considered to be a high priority area for economic evaluation for the following reasons: diagnostic testing has the potential to result in earlier diagnosis of organic disease which may improve health outcomes; the widespread use of tests may have significant cost implications; the use of tests may result in unnecessary anxiety for patients, particularly if the rate of false positive results is high; invasive tests may have adverse consequences for patients in terms of complications.

The use of pharmacological and behavioural interventions in the management of IBS was also identified as a high priority area for economic evaluation. Pharmacological interventions were identified as an area of high priority because the ongoing use of these interventions in a large number of IBS patients would have significant implications for the use of NHS resources. Behavioural interventions were identified as an area of high priority because these are not widely used at present in the management of IBS and therefore significant additional resources may be required if these are recommended for widespread use.

Two approaches were employed to provide cost-effectiveness evidence for the GDG to consider when making recommendations. Firstly, a review of the health economic literature was carried out and relevant health economic evidence was presented to the GDG. Secondly, further economic analysis was carried out in the priority areas where there was insufficient evidence available from the published literature to inform recommendations and where there was sufficient evidence to demonstrate the clinical effectiveness for the intervention or diagnostic strategy. This further economic analysis was conducted in the form of a cost-effectiveness analysis where the additional benefits were measured in terms of quality-adjusted life-years (QALYs) and the additional costs were assessed from a National Health Service (NHS) and personal social services perspective. The GDG considered the incremental cost per QALY for alternative management and diagnostic strategies alongside the clinical effectiveness evidence when formulating recommendations. Where one clinical strategy was clearly more effective and less costly than another it was considered cost-effective. Where one strategy was more effective but also more costly, the incremental cost per QALY was estimated and this was compared to a cost effectiveness threshold of 20,000 to 30,000 pounds sterling per QALY in line with the principals laid out in the NICE Guidelines Manual (NICE 2007). For those clinical questions not prioritised for economic analysis, the GDG considered the likely cost-effectiveness of associated recommendations by making a qualitative judgement on the likely balance of costs, health benefits and any potential harms.

See Section 5.3 in the full version of the guideline for methods and results of the cost-effectiveness review.

### 2015 Update

See Section 2 in the Addendum to NICE Guideline CG61, Irritable Bowel Syndrome in Adults (see the "Availability of Companion Documents" field) for the updated economic evidence review for each review question.

## Method of Guideline Validation

External Peer Review

Internal Peer Review

## Description of Method of Guideline Validation

The guideline was validated through two consultations.

1. The first draft of the guideline (the full guideline and the National Institute for Care Excellence (NICE) guideline) were consulted with Stakeholders and comments were considered by the Guideline Development Group (GDG)
2. The final consultation draft of the Full guideline, the NICE guideline and the Information for the Public were submitted to stakeholders for final comments.

The final draft was submitted to the Guideline Review Panel for review prior to publication.

## Evidence Supporting the Recommendations

### Type of Evidence Supporting the Recommendations

#### 2008 Guideline

Recommendations are based on clinical and cost effectiveness evidence, and where this is insufficient, the Guideline Development Group (GDG) used all available information sources and experience to make consensus recommendations using nominal group technique.

#### 2015 Update

The type of evidence supporting the recommendations is not specifically stated.

## Benefits/Harms of Implementing the Guideline Recommendations

### Potential Benefits

#### 2008 Guideline

Effective diagnosis and management of irritable bowel syndrome (IBS)

#### 2015 Update

Refer to the "Trade-off between benefits and harms" sections of Addendum to NICE Guideline CG61, Irritable Bowel Syndrome in Adults (see the "Availability of Companion Documents" field) for benefits of specific interventions.

### Potential Harms

#### 2008 Guideline

Adverse effects of medications

#### 2015 Update

Refer to the "Trade-off between benefits and harms" sections of Addendum to NICE Guideline CG61, Irritable Bowel Syndrome in Adults (see the "Availability of Companion Documents" field) for harms of specific interventions.

## Qualifying Statements

### Qualifying Statements

- This guidance represents the view of the National Institute for Health and Care Excellence (NICE), which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer, and informed by the summaries of

product characteristics of any drugs.

- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.
- This guideline recommends some medicines for indications for which they do not have a UK marketing authorisation at the date of publication, if there is good evidence to support that use. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. The patient (or those with authority to give consent on their behalf) should provide informed consent, which should be documented. See the General Medical Council's [Good practice in prescribing and managing medicines and devices](#) [redacted] for further information. Where recommendations have been made for the use of medicines outside their licensed indications ('off-label use'), these medicines are marked with a footnote in the recommendations.
- The guideline will assume that prescribers will use a drug's summary of product characteristics to inform decisions made with individual patients.
- Treatment and care should take into account individual needs and preferences. Patients should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. Healthcare professionals should follow the [Department of Health's advice on consent](#) [redacted]. If someone does not have capacity to make decisions, healthcare professionals should follow the [code of practice that accompanies the Mental Capacity Act](#) [redacted] and the supplementary [code of practice on deprivation of liberty safeguards](#) [redacted].
- NICE has produced guidance on the components of good patient experience in adult National Health Service (NHS) services. All healthcare professionals should follow the recommendations in [Patient experience in adult NHS services](#) [redacted].
- For all recommendations, NICE expects that there is discussion with the patient about the risks and benefits of the interventions, and their values and preferences. This discussion aims to help them to reach a fully informed decision (see also 'Patient-centred care').

## Implementation of the Guideline

### Description of Implementation Strategy

The National Institute for Health and Care Excellence (NICE) has developed tools to help organisations implement this guidance (see <http://www.nice.org.uk/Guidance/CG61> [redacted]; see also the "Availability of Companion Documents" field).

#### Key Priorities for Implementation

The following recommendations were identified as priorities for implementation in the 2008 guideline and have not been changed in the 2015 update.

#### Initial Assessment

- Healthcare professionals should consider assessment for irritable bowel syndrome (IBS) if the person reports having had any of the following symptoms for at least 6 months:
  - Abdominal pain or discomfort
  - Bloating
  - Change in bowel habit [2008]
- All people presenting with possible IBS symptoms should be asked if they have any of the following 'red flag' indicators and should be referred to secondary care for further investigation if any are present (see the NICE [Referral guidelines for suspected cancer](#) [redacted] (NICE clinical guideline 27), for detailed referral criteria where cancer is suspected):
  - Unintentional and unexplained weight loss
  - Rectal bleeding
  - A family history of bowel or ovarian cancer
  - A change in bowel habit to looser and/or more frequent stools persisting for more than 6 weeks in a person aged over 60 years [2008]
- All people presenting with possible IBS symptoms should be assessed and clinically examined for the following 'red flag' indicators and should be referred to secondary care for further investigation if any are present (see the NICE [Referral guidelines for suspected cancer](#) [redacted] (NICE clinical guideline 27), for detailed referral criteria where cancer is suspected):

- Anaemia
- Abdominal masses
- Rectal masses
- Inflammatory markers for inflammatory bowel disease

Measure serum CA125 in primary care in women with symptoms that suggest ovarian cancer in line with the National Guideline Clearinghouse (NGC) summary of the NICE guideline [Ovarian cancer. The recognition and initial management of ovarian cancer](#) (NICE clinical guideline 122). [2008]

- A diagnosis of IBS should be considered only if the person has abdominal pain or discomfort that is either relieved by defaecation or associated with altered bowel frequency or stool form. This should be accompanied by at least two of the following four symptoms:
  - Altered stool passage (straining, urgency, incomplete evacuation)
  - Abdominal bloating (more common in women than men), distension, tension or hardness
  - Symptoms made worse by eating
  - Passage of mucus

Other features such as lethargy, nausea, backache and bladder symptoms are common in people with IBS, and may be used to support the diagnosis. [2008]

### Diagnostic Tests

- In people who meet the IBS diagnostic criteria, the following tests should be undertaken to exclude other diagnoses:
  - Full blood count (FBC)
  - Erythrocyte sedimentation rate (ESR) or plasma viscosity
  - C-reactive protein (CRP)
  - Antibody testing for coeliac disease (endomysial antibodies [EMA] or tissue transglutaminase [TTG]) [2008]
- The following tests are not necessary to confirm diagnosis in people who meet the IBS diagnostic criteria:
  - Ultrasound
  - Rigid/flexible sigmoidoscopy
  - Colonoscopy; barium enema
  - Thyroid function test
  - Faecal ova and parasite test
  - Faecal occult blood
  - Hydrogen breath test (for lactose intolerance and bacterial overgrowth) [2008]

### Dietary and Lifestyle Advice

- People with IBS should be given information that explains the importance of self-help in effectively managing their IBS. This should include information on general lifestyle, physical activity, diet and symptom-targeted medication. [2008]
- Healthcare professionals should review the fibre intake of people with IBS, adjusting (usually reducing) it while monitoring the effect on symptoms. People with IBS should be discouraged from eating insoluble fibre (for example, bran). If an increase in dietary fibre is advised, it should be soluble fibre such as ispaghula powder or foods high in soluble fibre (for example, oats). [2008]

### Pharmacological Therapy

- People with IBS should be advised how to adjust their doses of laxative or antispasmodic agent according to the clinical response. The dose should be titrated according to stool consistency, with the aim of achieving a soft, well-formed stool (corresponding to Bristol Stool Form Scale type 4). [2008]
- Consider tricyclic antidepressants (TCAs) as second-line treatment for people with IBS if laxatives, loperamide or antispasmodics have not helped. Start treatment at a low dose (5 mg–10 mg equivalent of amitriptyline), taken once at night, and review regularly. Increase the dose if needed, but not usually beyond 30 mg.\* [2015]

\* At the time of publication (February 2015), TCAs did not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the [General Medical Council's Good practice in prescribing and managing medicines and devices](#)  for further information.

## Implementation Tools

### Audit Criteria/Indicators

Clinical Algorithm

Patient Resources

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

## Institute of Medicine (IOM) National Healthcare Quality Report Categories

### IOM Care Need

Getting Better

Living with Illness

### IOM Domain

Effectiveness

Patient-centeredness

## Identifying Information and Availability

### Bibliographic Source(s)

National Collaborating Centre for Nursing and Supportive Care. Irritable bowel syndrome in adults: diagnosis and management of irritable bowel syndrome in primary care. London (UK): National Institute for Health and Care Excellence (NICE); 2015 Feb. 37 p. (Clinical guideline; no. 61).

### Adaptation

Not applicable: The guideline was not adapted from another source.

### Date Released

2008 Feb (revised 2015 Feb)

### Guideline Developer(s)

National Collaborating Centre for Nursing and Supportive Care - National Government Agency [Non-U.S.]

### Source(s) of Funding

National Institute for Health and Care Excellence (NICE)



# Guideline Committee

Guideline Development Group

## Composition of Group That Authored the Guideline

### 2008 Guideline

*Group Members:* Mr Jonathan Blanchard-Smith, Patient/carer representative, The Gut Trust (formerly the IBS Network); Dr Ian Bullock, Director, National Collaborating Centre for Nursing and Supportive Care; Dr Jamie Dalrymple, General Practitioner, Norwich; Ms Sarah Davis, Senior Health Economist, National Collaborating Centre for Nursing and Supportive Care; Ms Jackie Eastwood, Specialist Pharmacist in Gastroenterology, St. Mark's Hospital, Harrow; Dr Charles Foster, Senior Researcher, University of Oxford; Dr Jenny Gordon, Research and Development Fellow, National Collaborating Centre for Nursing and Supportive Care; Mrs Jenny Gough, Nurse Consultant, Camden Primary Care Trust, London; Professor Elspeth Guthrie, Professor of Psychological Medicine & Medical Psychotherapy, Manchester Royal Infirmary; Dr Miranda Lomer, Consultant Dietician in gastroenterology, King's College London; Ms Marion Saunders, Patient/carer representative; Ms Theresa Shaw (*Chair*), Chief Executive, Foundation of Nursing Studies, London; Dr Richard Stevens, General Practitioner, Oxford; Dr Maggie Westby, Senior Research and Development Fellow, National Collaborating Centre for Nursing and Supportive Care; Professor Peter Whorwell (*Clinical Lead*), Professor of Medicine and Gastroenterology, Wythenshawe Hospital, Manchester; Dr Mary Wilson, Nurse Specialist, Westwood Hospital, North Humberside

### 2015 Update

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## Financial Disclosures/Conflicts of Interest

### 2008 Guideline

All members of the Guideline Development Group (GDG) were required to make formal declarations of interest at the outset, and these were updated at every subsequent meeting throughout the development process. This information is recorded in the meeting minutes and kept on file at the National Collaborating Centre for Nursing and Supportive Care (NCC-NSC). The GDG declarations are recorded in Appendix K in the full version of the original guideline document.

### 2015 Update

See Section 4.4 in the original guideline document for declarations of interests. All other members stated that they had no interests to declare.

## Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: National Collaborating Centre for Nursing and Supportive Care. Irritable bowel syndrome in adults. Diagnosis and management of irritable bowel syndrome in primary care. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Feb. 27 p. (Clinical guideline; no. 61).

This guideline meets NGC's 2013 (revised) inclusion criteria.

## Guideline Availability

Electronic copies: Available from the [National Institute for Health and Care Excellence \(NICE\) Web site](#) . Also available for download in ePub and eBook formats from the [NICE Web site](#) .

## Availability of Companion Documents

The following are available:

- Irritable bowel syndrome in adults: diagnosis and management of irritable bowel syndrome in primary care. Full guideline. London (UK): National Institute for Health and Care Excellence (NICE); 2008 Feb. 553 p. (Clinical guideline; no. 61). Electronic copies: Available from the [National Institute for Health and Care Excellence \(NICE\) Web site](#) .
- Irritable bowel syndrome in adults: diagnosis and management of irritable bowel syndrome in primary care. Full guideline appendices A-K. London (UK): National Institute for Health and Care Excellence (NICE); 2008 Feb. (Clinical guideline; no 61). Electronic copies: Available from the [NICE Web site](#) .
- Addendum to NICE guideline CG61, irritable bowel syndrome in adults: diagnosis and management of irritable bowel syndrome in primary care. NICE guideline CG61.1. Methods, evidence and recommendations. London (UK): National Institute for Health and Care Excellence (NICE); 2015 Feb. 319 p. (Clinical guideline; no. 61). Electronic copies: Available from the [NICE Web site](#) .
- Irritable bowel syndrome in adults: diagnosis and management of irritable bowel syndrome in primary care. Costing template. London (UK): National Institute for Health and Care Excellence (NICE); 2008 Feb. (Clinical guideline; no. 61). Electronic copies: Available from the [NICE Web site](#) .
- Irritable bowel syndrome in adults: diagnosis and management of irritable bowel syndrome in primary care. Costing report. London (UK): National Institute for Health and Care Excellence (NICE); 2008 Feb. 39 p. (Clinical guideline; no. 61). Electronic copies: Available from the [NICE Web site](#) .
- Irritable bowel syndrome in adults: diagnosis and management of irritable bowel syndrome in primary care. Costing statement. London (UK): National Institute for Health and Care Excellence (NICE); 2015 Feb. 4 p. (Clinical guideline; no. 61). Electronic copies: Available from the [NICE Web site](#) .
- Irritable bowel syndrome in adults: diagnosis and management of irritable bowel syndrome in primary care. Audit support. London (UK): National Institute for Health and Care Excellence (NICE); 2008. 12 p. (Clinical guideline; no. 61). Electronic copies: Available from the [NICE Web site](#) .
- Irritable bowel syndrome in adults: diagnosis and management of irritable bowel syndrome in primary care. Baseline assessment tool. London (UK): National Institute for Health and Care Excellence (NICE); 2015 Feb. (Clinical guideline; no. 61). Electronic copies: Available from the [NICE Web site](#) .
- The guidelines manual 2012. London (UK): National Institute for Health and Care Excellence (NICE); 2012 Nov. Electronic copies: Available in from the [NICE Web site](#) .

## Patient Resources

The following is available:

- Irritable bowel syndrome in adults: diagnosis and management of irritable bowel syndrome in primary care. Information for the public. National Institute for Care Excellence (NICE); 2015 Feb. 14 p. Available from the [National Institute for Health and Care Excellence \(NICE\) Web site](#) . Also available for download in ePub and eBook formats from the [NICE Web site](#) . Also available in Welsh from the [NICE Web site](#) .

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## NGC Status

This summary was completed by ECRI Institute on April 9, 2009. The currency of the guideline was reaffirmed by the developer in 2011 and this summary was updated by ECRI Institute on October 30, 2013. This summary was updated by ECRI Institute on April 1, 2015.

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