National Institute for Clinical Excellence

Irritable bowel syndrome Scope Stakeholder Consultation Table

March 2006

SH organisation	No.	Section no.	Comments	Developers' response
Addenbrookes NHS Trust	1	4.3.1. (d)	Prebiotics and probiotics should be included.	Thank you for your response. Prebiotics and probiotics have been added to the scope in section 4.3.1 b.
Amgen UK Ltd			This organisation was approached but did not respond.	
Association for Continence Advice			This organisation was approached but did not respond.	
Association of Child Psychotherapists			This organisation was approached but did not respond.	
Association of Coloproctology of Great Britain and Ireland			This organisation was approached but did not respond.	
Barnsley Primary Care Trust			This organisation was approached but did not respond.	
BHF Health Promotion Research Group	1	3	In addition to identifying trends the guidance should attempt to identify possible and known variables associated with IBS, any interactions of these variables and their place within any causal pathways. This will allow greater confidence and precision in making recommendations about prevention, treatment and management of IBS.	Thank you for your comment. This will be addressed in the guideline.
BHF Health Promotion Research Group	2	4.3	If exercise is suggested as a therapeutic option for treatment or management of IBS (and hinted at in prevention), will these recommendations be based upon trial evidence? If no evidence is available then what type of recommendation should or could be made? This recommendation must include tailoring of any dose of activity in terms of FITT principles. (Frequency, Intensity, Time and Type of exercise). Any recommendation must take into account co-morbidities and physical limitations. Any recommendations for health professional must reflect guidance from Public Health interventions	Thank you for your comments. The preferred study design for therapeutic options will be the randomised trial. Where such evidence is not available, recommendations will be based on consensus decisions. Regarding your second point. These principles have been included in the scope.

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			(available on 30th March).	
BHF Health Promotion Research Group	3	General	We support any review that tackles prevention of chronic disease but feel there should be sufficient evidence to identify and support any recommendations (upon high quality epidemiological evidence). We feel that encouraging sedentary adults and children to be more active will offer relief to symptoms associated with IBS, e.g. stress, anxiety, depression, back pain. However these conditions in themselves need care consideration of what is an appropriate exercise prescription.	Following consultation the Department of Health has agreed to remove prevention from the remit.
BHF Health Promotion Research Group	4	General	Can the recommendations make research recommendations, similar to NICE Public Health recommendations?	All clinical guidelines are expected to make research recommendations Any research recommendations would take into consideration relevant recommendations made by NICE Public Health.
BHF Health Promotion Research Group	5	General	We would like to see better integration of clinical guidelines and public health guidelines, especially if prevention appears to be addressed in both areas. If behavioural interventions, such as physical activity as part of chronic disease management, are to be found in NICE Clinical guidelines we would like NICE to consider establishing one point of reference for these specialist areas that could service other clinical areas also.	Following consultation the Department of Health has agreed to remove prevention from the remit. Behavioural interventions such as physical activity are being considered as part of this guideline and support the view that there should be one point of reference for these specialist areas to ensure consistency of information.
Boehringer Ingelheim Ltd			This organisation was approached but did not respond.	
Bristol North PCT (Teaching)	1	3.(b)	We consider that it is important that the development of the guideline does not lead to increased medicalisation of this syndrome. The BGS guidelines are helpful in this regard.	Thank you for your comment. The guidance aims to ensure that IBS is accurately diagnosed and managed effectively to prevent increased medicalisation and unnecessary treatments.
Bristol North PCT (Teaching)	2	3.(b)	How relevant is NHS Direct online data at assessing treatment patterns, since this is likely to be educationally and socially imbalanced. However we would not dispute that a significant number of patients do not view this as a condition which requires medicalisation. Consequently it is important for a significant emphasis to be given within the guideline on self-care and self- management	Thank you for your comments. We agree that there will be some imbalance when using NHS Direct online data. This is used as an indication of the current situation. Self care and self management is covered by this guideline. However, this should be viewed in the context of how it interacts with primary care, e.g. as recommended by primary care clinicians.

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			techniques.	
Bristol North PCT (Teaching)	3	3.(i)	We note that this refers to "primary care" and we would consider that community pharmacy, as well as media options, should be the first place for self-care guidance. General practice, does not in our consideration, need to become the starting place for self-care guidance, since this implies that there is a need for medicalisation, with subsequent referral and intensive therapy.	Thank you for your comments. General Practice is considered to be the starting point as NICE guidance is concerned with management within the NHS. Self care guidance without medical support via the media or community pharmacy is acknowledged in the patient pathway. The Royal Pharmaceutical Society of Great Britain has nominated a representative for the GDG.
Bristol North PCT (Teaching)	4	3 (c)	Request that "food allergy testing" be positioned within this guideline. We believe that this may be an area of private expenditure by IBS suffers and needs to be critiqued within this guideline.	Thank you for your comments. This has been included in dietary management.
Bristol North PCT (Teaching)	5	3 (c)	We hope that there will be clarity about gluten intolerance, since failure to do so may manifest itself as pressure for GP prescription. There should be unambiguous diagnostic criteria for gluten sensitivity, which we understand to be biopsy, without which NHS prescription is impossible.	This will be covered as part of alternative diagnosis investigations and included in dietary management.
Bristol North PCT (Teaching)	6	4.3.2	Should any of the new drugs excluded from this guideline come to the UK market during the guideline, it is important that their place within treatment is defined. The guideline development programme is sufficiently long for this to occur and it will devalue the utility of the final guideline if new products are not given a position within treatment, regardless of whether a TAG is subsequently sought.	Thank you for your comments. Section 4.3.2 has been clarified.
British Association for Behavioural and Cognitive Psychotherapies (BABCP)	1	General	BACP welcome the development of this clinical guideline and are pleased that the impact of stress on this condition is recognised.	Thank you.
British Association for Behavioural and Cognitive Psychotherapies (BABCP)	2	4.3.1 d) (p.5)	Whilst the scope includes reference to non-pharmaceutical treatments such as cognitive behavioural therapy (CBT), we would argue that to include only CBT as a form of psychological therapy it too narrow; there may be evidence that other interventions work. We therefore believe this would	Thank you for your response. We will add 'other psychotherapeutic interventions' to section 4.3.1 b.

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			best be reworded as, for example: 'Non-pharmacological treatments, including a range of therapeutic treatment such as cognitive behavioural therapy **and other psychotherapeutic interventions,** acupuncture, Chinese herbal medicine, hypnotherapy, meditation, reflexology and aromatherapy.'	
British Association for Counselling and Psychotherapy (BACP)			This organisation was approached but did not respond.	
British Dietetic Association		General	Thank you for giving The British Dietetic Association the opportunity to comment on this guidance.	Thank you.
British Dietetic Association		4.3.1 d)	Dietary treatment should be added.	Thank you for your comment. This has been added to section 4.3.1 b.
British Dietetic Association		4.3.1 d)	Probiotics should be added.	Thank you for your comment. This has been added to the scope in section 4.3.1 b.
British Geriatrics Society - Gastro-enterology and Nutrition Special Interest Group	1	General	IBS is a common disorder, IBS is traditionally considered to be a condition that primarily affects young and middle-aged adults. However, increasing evidence suggests that prevalence of IBS in older adults may be similar to that in younger adults; therefore, the diagnosis should be considered when an elderly patient presents with unexplained abdominal symptoms. Because incidences of other conditions with similar symptoms are higher in the elderly population, use of certain diagnostic test is warranted in this patient population. In addition, because older adults are more likely than younger adults to suffer from comorbid conditions, polypharmcy is common in this patient population, and this should be considered when diagnosing and treating these patients.	Thank you for your comments. This has been included in section 3c.
British National Formulary (BNF)			This organisation was approached but did not respond.	
British Nuclear Medicine Society			This organisation was approached but did not respond.	

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British Society of Gastroenterology	1	Title	From the currently available data on IBS it is unlikely that any meaningful comments can be made about prevention. However, this is obviously an important point and would possibly be better dealt with in a section on suggestions for future research rather than having it in the title as a primary objective.	Following consultation the Department of Health has agreed to remove prevention from the remit.
British Society of Gastroenterology	2	Section 3i	In this section it might be worth having another bullet point called "Clinical presentation". It has previously been shown that if a non-colonic feature of IBS is especially severe (eg a gynaecological symptom) the patient may be referred to the wrong specialty where the outcome is poor. Obviously this type of referral decision is being taken at the primary care level and better knowledge of this problem would almost certainly reduce inappropriate referrals.	Thank you. This point has been added to section 3e.
CIS'ters			This organisation was approached but did not respond.	
Coeliac UK	1	General	**Re: Role of patient/carer representatives** Voluntary organizations are not only contributing from the patient/carer perspective in a subjective or qualitative way but that some organizations are in fact currently engaged in doing research for peer review and so could also contribute objective data to the consultation. In addition, voluntary organizations work in conjunction with medical advisers who are experts in the field and may collaborate with key researchers at any one time in order to present evidence based statements.	Thank you for your comments. Stakeholders are encouraged to submit relevant research evidence as described in The guideline development Process-An Overview for Stakeholders, the Public and the NHS (pg iv).
Coeliac UK	2	General	**Re: Guideline scope discussion** Coeliac disease and IBS have comparable symptoms and presentation and there is evidence both anecdotally and peer reviewed to support the case that patients are misdiagnosed in primary care with IBS without having excluded coeliac disease (ie the Rome II criteria are not applied). Screening studies involving patients with IBS indicate that there is a higher prevalence of coeliac disease in this group. [1,2] There is also evidence of under-	Thank you for your comments. This point will be considered and has been added to section 4.3.1 (a) The guideline will focus on the patient journey which usually starts in primary care. It will cover the clinical and cost criteria for referral to secondary care, addressing relevant investigations and treatments in whichever setting these are performed. The scope has been re-worded to reflect this

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			diagnosis of coeliac disease with a diagnosed population of 125,000 in the UK[3] compared against a prevalence of 1 in 100.[4] Although there is a clear process for diagnosis of coeliac disease involving blood tests which can be performed in primary care that detect antibodies (tissue transglutaminase and anti-endomysial antibodies) followed by endoscopy of the jejunal area of the gut with biopsy the process is hampered. There is a lack of awareness of coeliac disease in primary care which results in patients self-diagnosing and trying a gluten-free diet, prior or during the process of diagnosis. This can result in false negative results. In addition, a wheat-free diet can be applied to treat IBS and this will have the same effect if diagnosis of coeliac disease is pursued during treatment. Complementary therapists may also recommend dietary change for IBS patients which may not be evidence based and which may again complicate or confuse the treatment and diagnosis of patients with IBS – or those misdiagnosed who may have coeliac disease.	
Coeliac UK	3	Refs	1. Sanders DS, Patel D, Stephenson TJ, Ward AM, McCloskey EV, Hadjivassiliou M, Lobo AJ. A primary care cross-sectional study of undiagnosed adult coeliac disease. Eur J Gastroenterol Hepatol. 2003 Apr;15(4):407-13 2 Hin H, Bird G, Fisher P, Mahy N, Jewell D. Coeliac disease in primary care: case finding study. *BMJ* 1999; 318: 164-167 [3] The missing reference quoting a population of 125,000 is as follows: DA van Heel, J West Recent Advances in clinical practice: coeliac disease Gut 2006 (IN PRESS) [4] West J, Logan RF, Hill PG, Lloyd A, Lewis S, Hubba Khaw KT. Seroprevalence, correlates, and characteristics of undetected coeliac disease in	

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			England. Gut. 2003 Jul;52(7):960-5	
Coloplast Limited			This organisation was approached but did not respond.	
Commission for Social Care Inspection			This organisation was approached but did not respond.	
Connecting for Health			This organisation was approached but did not respond.	
Continence Foundation	1	3g	Since a number of these investigations are carried out in secondary more often than primary care, the opening of this paragraph needs to be revised.	Thank you for your comments, this paragraph has been revised. The guideline will focus on the patient journey, which usually starts in primary care. It will cover the clinical and cost criteria for referral to secondary care, addressing relevant investigations and treatments in whichever setting these are performed. The scope has been re-worded to reflect this.
Continence Foundation	2	3a	Rome II criteria: a search of the internet suggests there is more to the criteria than this – other symptoms that would assist with diagnosis if present. Since many patients present a long time after onset, they may not remember changes that took place then. The additional symptoms would then be needed to confirm diagnosis.	Thank you for your comments. The guideline will look at different diagnostic methods of which Rome II is one; the paragraph has been revised to reflect this.
Conwy and Denbighshire NHS Trust			This organisation was approached but did not respond.	
Counsellors and Psychotherapists in Primary Care			This organisation was approached but did not respond.	
Department for Education and Skills			This organisation was approached but did not respond.	
Department of Gastroenterology	1	4.3.2	Some patients are resistant to the measures so far mentioned.	Thank you for your comment.
Department of Gastroenterology	2		The place of 5HT3 and 5HT4 drugs should be reviewed.	Section 4.3.2. has been clarified.
Department of Gastroenterology	3	4.1	There should be focus on why some patients present and others do not, despite apparently similar symptoms.	Thank you for your comment. This is an interesting point, but outside the scope of this guideline.
Department of Health	1	General	You may like to refer to the PRODIGY guidelines, which already exist for IBS. Details are available at http://www.prodigy.nhs.uk/ProdigyKnowledge/Guida	Thank you for your comments, other evidence based guidelines will be reviewed as part of the development process.

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			nce/GuidanceView.aspx?GuidanceId=56279 This guide covers diagnosis and treatment (including the need for referral) and patient information leaflets.	
Ferring Pharmaceuticals Limited	1	3C	Here it mentions that some IBS patients have abnormal colonic flora, there is no mention of possible correction of this in the management section.	Thank you for your comment. Possible correction of abnormal colonic flora may be addressed by the use of probiotics included in section 4.3.1 b.
Ferring Pharmaceuticals Limited	2	4.3.1b,c, d	We would like to see probiotics included here as a possible treatment for IBS or treatment for the relief of symptoms of IBS. The management covers self management, drug treatment and non drug treatment. Probiotics fall somewhere in between all three and we feel it is important that these are covered in the treatment guidelines.	Thank you for your comments pre and probiotics have been added to section 4.3.1 b.
First Steps to Freedom			This organisation was approached but did not respond.	
Health and Safety Executive			This organisation was approached but did not respond.	
Healthcare Commission			This organisation was approached but did not respond.	
Heart of England NHS Foundation Trust			This organisation was approached but did not respond.	
Incontact (Action on Incontinence)	1	General	Limiting the scope to primary care restricts patient choice over where they receive investigations interventions and care.	Thank you for your comment. The guideline will focus on the patient journey, which usually starts in primary care. It will cover the clinical and cost criteria for referral to secondary care, addressing relevant investigations and treatments in whichever setting these are performed. The scope has been re-worded to reflect this.
Incontact (Action on Incontinence)	2	General	It is important that the needs of those with pre existing disabilities are taken into account (DDA 1995 and 2005). This may have an impact on access to investigations, interventions and care so that inequalities in healthcare do not occur. A recent report by the HCC and DRC showed gross inequalities in access to healthcare by those with learning disabilities. The new Disability Equality Duty comes into force in Dec 2006.	Thank you for your comment The consideration of the specific needs of patients with disabilities are implicit in NICE guidance.

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Incontact (Action on Incontinence)	3	3f	Investigations available in primary care may not pick up patients who have a non functional cause for their symptoms e.g. those with coeliac disease.	Thank you for your comment. The guideline will focus on the patient journey, which usually starts in primary care. It will cover the clinical and cost criteria for referral to secondary care, addressing relevant investigations and treatments in whichever setting these are performed. The scope has been re-worded to reflect this.
Incontact (Action on Incontinence)	4	3i	Clinical and cost effective indications for referral into secondary care do not take account of individual patient needs and preferences. Referral to a specialist unit may be needed to reassure a patient that their symptoms do not have a more sinister cause. The latter may be needed for the patient to learn to self manage and avoid a continuing drain on primary care resources by frequent visits to clinicians.	Thank you for your comment. This point has been included in section 4.2.
Incontact (Action on Incontinence)	5	4.1	It is important that no population is accidentally excluded e.g. older people or those with any type of disability (see DDA 2005 for definition of disability) The latter may need special consideration.	Thank you for your comment. The consideration of the specific needs of patients with disabilities are implicit in NICE guidance.
Incontact (Action on Incontinence)	6	4.2	Secondary specialist gastrointestinal or continence services should not be excluded. These provide more appropriate care for some patients presenting with IBS symptoms. Patients require choice.	Thank you for your comment. The guideline will focus on the patient journey, which usually starts in primary care. It will cover the clinical and cost criteria for referral to secondary care, addressing relevant investigations and treatments in whichever setting these are performed. The scope has been re-worded to reflect this.
Incontact (Action on Incontinence)	7	4.3.1a	ROME criteria are research not patient focussed.	Thank you for your comments. The guideline will look at different diagnostic methods of which Rome II is one, paragraph 3a has been revised to reflect this.
Incontact (Action on Incontinence)	8	4.3.1b	It is important that patients who are taught self management techniques have dietary advice from appropriately trained health care professionals. Many IBS patients end up with nutritional deficiencies or unnecessarily restricted diets due to inappropriate advice. Dietary exclusion of wheat or gluten before investigations are carried out may lead to a false negative result for coeliac disease. Any exercise regime must be appropriate for the individual patient. The needs of older people or	Thank you for your comment. The guideline will focus on the patient journey, which usually starts in primary care. It will cover the clinical and cost criteria for referral to secondary care, addressing relevant investigations and treatments in whichever setting these are performed. The scope has been re-worded to reflect this.

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			those who have a coexisting disability must be considered.	
Incontact (Action on Incontinence)	9	4.3.1e	Hopefully new drugs that are given licences during the guideline development process will be covered.	Thank you for your comment. Section 4.3.2 has been clarified.
Institute of Psychiatry - Kings College London			This organisation was approached but did not respond.	
ME Association			This organisation was approached but did not respond.	
Medicines and Healthcare Products Regulatory Agency (MHRA)			This organisation was approached but did not respond.	
Mental Health Act Commission			This organisation was approached but did not respond.	
National Association for Colitis and Crohns Disease (NACC)			This organisation was approached but did not respond.	
National Association of British and Irish Millers			This organisation was approached but did not respond.	
National Patient Safety Agency			This organisation was approached but did not respond.	
National Phobics Society			This organisation was approached but did not respond.	
National Public Health Service - Wales			This organisation was approached but did not respond.	
National Treatment Agency for Substance Misuse			This organisation was approached but did not respond.	
NHS Health and Social Care Information Centre			This organisation was approached but did not respond.	
NHS Plus			This organisation was approached but did not respond.	
NHS Quality Improvement Scotland			This organisation was approached but did not respond.	
Norgine Ltd			This organisation was approached but did not respond.	
North Sheffield PCT			This organisation was approached but did not respond.	
Northwick Park and St Mark's Hospitals NHS	1	4.3.1.d	Non-pharmacological therapies-this must surely include psychodynamic psychotherapy as per the	Thank you for your response. Other psychotherapeutic interventions have been added to

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Trust			work of Guthrie and Creed.	section 4.3.1 d .
Northwick Park and St Mark's Hospitals NHS Trust	2	4.3.1 a	Diagnosis should include a brief assessment for anxiety disorders, mood disorders and somatoform disorders – many patients will have these co-morbidities which may impact on further treatment and secondary care referral.	Thank you for your comment. 4.3.1.a has been revised to include your comment.
Northwick Park and St Mark's Hospitals NHS Trust	3	4.3.1 a	Should the role of faecal calprotectin in the diagnosis of IBS be included?	Thank you for your comment. The role of faecal calprotein will be considered as one of the diagnostic investigations for IBS.
Northwick Park and St Mark's Hospitals NHS Trust	4	4.3.1 a	Patient self- management should include an emphasis of education with the aid of multi-media formats.	Thank you we have included 'information, education and support for patients, families and carers' in section 4.3.1 e.
Northwick Park and St Mark's Hospitals NHS Trust	5	4.3.1.d	This might also include probiotics.	Thank you. We have added probiotics to section 4.3.1 b.
Novartis Pharmaceuticals UK Ltd			This organisation was approached but did not respond.	
Nutrition Society			This organisation was approached but did not respond.	
Oxford Nutrition Ltd			This organisation was approached but did not respond.	
PERIGON (formerly The NHS Modernisation Agency)			This organisation was approached but did not respond.	
Procter and Gamble Pharmaceuticals			This organisation was approached but did not respond.	
Reckitt Benckiser Healthcare (UK) Ltd			This organisation was approached but did not respond.	
Royal College of General Practitioners			This organisation was approached but did not respond.	
Royal College of Nursing	1	General	With a membership of over 380,000 registered nurses, midwives, health visitors, nursing students, health care assistants and nurse cadets, the Royal College of Nursing (RCN) is the voice of nursing across the UK and the largest professional union of nursing staff in the world. The RCN promotes patient and nursing interests on a wide range of issues by working closely with Government, the UK parliaments and other national and European	

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			political institutions, trade unions, professional bodies and voluntary organisations.	
Royal College of Nursing	2	Section 3 f	"Strong" family history, this seems subjective - as any family history should be assessed by a family history clinic/genetics. The GP could also refer directly to genetic services regarding advice on this following his/her interpretation of "strong".	Thank you. 'Strong' has been removed.
Royal College of Nursing	3	General	It is noted that the draft scope for this guidance proposes that IBS be diagnosed then managed in primary care. It also specifies including the criteria for referral to secondary care at the end of the draft but it is not clear what these are.	Thank you for your comment. The guideline will focus on the patient journey, which usually starts in primary care. It will cover the clinical and cost criteria for referral to secondary care, addressing relevant investigations and treatments in whichever setting these are performed. The scope has been re-worded to reflect this.
Royal College of Nursing	4	Section 3 g	For instance, some of the functions listed under areas to be covered relating to diagnosis are undertaken in secondary care. IBS is a negative diagnosis arrived at following clinical presentation of a group of symptoms followed by appropriate investigations with no positive findings. Many of those suggested perhaps would not be performed in primary care i.e. lactose intolerance test (hydrogen breath test, stool acidity test and exclusion diets), transit studies, barium studies and endoscopy. Even sigmoidoscopy, rigid or otherwise would rarely be carried out in primary care with most surgeries at best performing only proctoscopy or simply digital rectal examination.	Thank you for your comment. The guideline will focus on the patient journey, which usually starts in primary care. It will cover the clinical and cost criteria for referral to secondary care, addressing relevant investigations and treatments in whichever setting these are performed. The scope has been re-worded to reflect this.
Royal College of Nursing	5	Section 3 g	Clarification on investigations is required. It is recognised that in some practices, primary care investigations will include Abdominal examination, rectal examination, +/- rigid sigmoidoscopy/proctoscopy, (sigmoidoscopy is too vague). Transit studies, however, would be done in secondary care and not sure if GPs would request that as an initial examination, and if they did it would only be for constipation dominant IBS. Barium enema is not carried out for patients with family	Thank you for your comments. The guideline will focus on the patient journey, which usually starts in primary care. It will cover the clinical and cost criteria for referral to secondary care, addressing relevant investigations and treatments in whichever setting these are performed. Investigations that will be included have been clarified. The scope has been re-worded to reflect this.

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			history of bowel cancer, it is only Colonoscopy and this is only via referral to a specialist/ via a genetics clinics. Suggest this should be removed, from this section as it is mentioned in section 3 f.	This has been removed as suggested.
Royal College of Nursing	6	Section 3 g	Anti endomysial/antigliaden antibody test is no longer used to exclude coeliac disease and anti tissue transglutaminase (anti TTG) is now used instead as this is thought to be more specific and sensitive. However around 10% of cases can still be missed. Other blood tests listed include thyroid function but there is no mention of Full Blood Count (FBC), Liver Function Tests (LFTs), Urea and Electrolytes (U+Es) and inflammatory markers which of course are essential.	The guideline will focus on the patient journey, which usually starts in primary care. It will cover the clinical and cost criteria for referral to secondary care, addressing relevant investigations and treatments in whichever setting these are performed. Investigations that will be included have been clarified. The scope has been re-worded to reflect this.
Royal College of Nursing	7	Section 3 g	Also the sentence on investigating over the age of 45 years, this is subjective as many trusts offer different clinics, for example some run a clinic for the under 40's, who are investigated with flexible sigmoidoscopy.	Thank you – the specified age group of 45 years and over has been changed to 40 in line with the recommendations for NICE guidance on referral for suspected cancer.
Royal College of Nursing	8	Section 3.i	Prevention may be difficult to address as cause is "unknown".	Following consultation the Department of Health has agreed to remove prevention from the remit.
Royal College of Nursing	9	Section 4.2	As stated earlier, the arbitrary demarcation between primary and secondary care is not useful. While the guideline should clearly state referral guidelines from primary to secondary care, it should not address where care is to be given as this depends on local service configuration. So the guideline should cover ALL treatments for IBS wherever they are delivered.	Thank you for your comment. The guideline will focus on the patient journey, which usually starts in primary care. It will cover the clinical and cost criteria for referral to secondary care, addressing relevant investigations and treatments in whichever setting these are performed. The scope has been re-worded to reflect this.
Royal College of Nursing	10	Section 4.1.2	Why 12 years old? Especially if prevention is discussed, should include all age groups.	Thank you for your comments. Given the difference in the impact of IBS and the different approaches that may be required for the diagnosis and management of the condition in children, it is the recommendation of the NCC-NSC that separate guidance is produced. On this basis, children are not included in the scope. Guideline topic suggestions can be submitted to the Department of Health via the NICE website. http://www.nice.org.uk.

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Royal College of Nursing	11	Section 4.3 d	Remove "cognitive" just make it behavioural therapy, as some clinics use a modified behavioural therapy, which is not CBT. It makes it more inclusive then.	Thank you for your comment. Cognitive behavioural therapy has been retained as a specific intervention but other psychotherapeutic interventions have been included in section 4.3.1 d.
Royal College of Nursing	12	Section 4.3.1	Should this also include the use of pre and pro-biotics?	Thank you. We have added pre and probiotics to section 4.3.1 b.
Royal College of Nursing	13	Section 4.3.1	The Rome II criteria whilst widely accepted in assisting in the diagnosis are not in themselves a diagnosis of IBS. The differential diagnosis for IBS is wide including colorectal cancer and ovarian cancer. This will require some secondary care function - the GP may not be able to take action on this in primary care without secondary care referral first to exclude organic disease. If findings are subsequently negative then a decision could be made to manage in primary care with a number of options available as indicated in the document.	Thank you for your comments. The guideline will look at different diagnostic methods of which Rome II is one, paragraph 3a has been revised to reflect this. With regard to secondary care referral for differential diagnosis, the guideline will focus on the patient journe,y which usually starts in primary care. It will cover the clinical and cost criteria for referral to secondary care, addressing relevant investigations and treatments in whichever setting these are performed. The scope has been re-worded to reflect this.
Royal College of Nursing	14	General	The scope is comprehensive and seems realistic.	Thank you.
Royal College of Paediatrics and Child Health	1	3e	Morbidities of IBS in young people may also include school refusal/attendance and attention should be paid to the impact of exam stress on worsening symptoms thereby affecting exam performance. In many cases the medical team will need to liaise with education.	Thank you for your comments. Given the difference in the impact of IBS and the different approaches that may be required for the diagnosis and management of the condition in children, it is the recommendation of the NCC-NSC that separate guidance is produced. On this basis, children are not included in the scope. Guideline topic suggestions can be submitted to the Department of Health via the NICE website. http://www.nice.org.uk.
Royal College of Paediatrics and Child Health	2	3g	In young people with suspected IBS, some paediatricians exclude coeliac by using tissue transglutaminase (ttg) antibodies rather than endomysial antibodies. It is also noted that paediatricians may screen out for inflammatory bowel disorder as well, with FBC/platelets, CRP and possibly alpha1 acid glycoprotein, and albumin but most wouldn't use sigmoidoscopy/colonoscopy unless these screening tests were positive.	Thank you for your comments. Given the difference in the impact of IBS and the different approaches that may be required for the diagnosis and management of the condition in children, it is the recommendation of the NCC-NSC that separate guidance is produced. On this basis, children are not included in the scope. Guideline topic suggestions can be submitted to the Department of Health via the NICE website. http://www.nice.org.uk.
Royal College of Paediatrics and Child Health	3	3g	As a strong family history often occurs in IBS, it may increase the difficulty of distinguishing real and imagined symptoms.	Thank you for your comments. Given the difference in the impact of IBS and the different approaches that may be required for the diagnosis and management of the condition in children, it is the

SH organisation	No.	Section no.	Comments	Developers' response
				recommendation of the NCC-NSC that separate guidance is produced. On this basis, children are not included in the scope. Guideline topic suggestions can be submitted to the Department of Health via the NICE website. http://www.nice.org.uk.
Royal College of Paediatrics and Child Health	4	4.1.1	The college notes that the guideline includes only young people over 12 years of age. Although this seems a sensible cut off point as it is acknowledged that young people over this age are likely to follow the 'adult model', it is disappointing that younger children are not covered, specifically as it acknowledges in section 3d that IBS is the commonest cause of abdominal pain in children and young people. Do NICE have any plans to complete separate guidance for the younger age group?	Thank you for your comments. Given the difference in the impact of IBS and the different approaches that may be required for the diagnosis and management of the condition in children, it is the recommendation of the NCC-NSC that separate guidance is produced. On this basis, children are not included in the scope. Guideline topic suggestions can be submitted to the Department of Health via the NICE website. http://www.nice.org.uk.
Royal College of Paediatrics and Child Health	5	4.3.1 c	The college notes that some of the treatments for IBS may be licensed for adults but not for children and young people.	Thank you for your comments. Given the difference in the impact of IBS and the different approaches that may be required for the diagnosis and management of the condition in children, it is the recommendation of the NCC-NSC that separate guidance is produced. On this basis, children are not included in the scope. Guideline topic suggestions can be submitted to the Department of Health via the NICE website. http://www.nice.org.uk.
Royal College of Physicians of London			This organisation was approached but did not respond.	
Royal College of Psychiatrists		Title	The title states it is about adults yet the scope says is 12 years and older- the title should reflect this.	Thank you for your comments. Given the difference in the impact of IBS and the different approaches that may be required for the diagnosis and management of the condition in children, it is the recommendation of the NCC-NSC that separate guidance is produced. On this basis, children are not included in the scope. Guideline topic suggestions can be submitted to the Department of Health via the NICE website. http://www.nice.org.uk.
Royal College of Psychiatrists	1	General	It is important that the guideline development group includes a psychiatrist with expertise in IBS.	Thank you for your comment – a nominee from the RCP has agreed to participate in the GDG.
Royal College of Psychiatrists	2	3	The guideline needs to refer in this section to the associated prevalence of psychological symptoms	Thank you for your comments. Given the difference in the impact of IBS and the different approaches

SH organisation	No.	Section no.	Comments	Developers' response
			in patients with IBS and the increased likelihood of childhood sexual abuse in comparison with the general population. The guideline needs to address the psychological aspects of IBS in the primary care setting. The change in focus re disease management means that more patients with IBS who are seen in secondary care will now be treated in primary care. This needs to be considered.	that may be required for the diagnosis and management of the condition in children, it is the recommendation of the NCC-NSC that separate guidance is produced. On this basis, children are not included in the scope. Guideline topic suggestions can be submitted to the Department of Health via the NICE website. http://www.nice.org.uk. Psychological aspects of IBS will be addressed in the guideline. The guideline will focus on the patient journey, which usually starts in primary care. It will cover the clinical and cost criteria for referral to secondary care, addressing relevant investigations and treatments in whichever setting these are performed. The scope has been re-worded to reflect this.
Royal College of Psychiatrists	3	4	Psychological treatments need to be included as well as antidepressants and other interventions.	Thank you for your comments. This point had been added to section 4.3.1d.
Royal College of Surgeons	1	1 and 4.2	Primary care exclusively?	The guideline will focus on the patient journey, which usually starts in primary care. It will cover the clinical and cost criteria for referral to secondary care, addressing relevant investigations and treatments in whichever setting these are performed. Investigations that will be included have been clarified. The scope has been re-worded to reflect this.
Royal College of Surgeons	2	1	Prevention of IBS is a bit of a tough one!	Following consultation the Department of Health has agreed to remove prevention from the remit.
Royal Liverpool Children's NHS Trust	1	General	When considering IBS in children school absenteeism or being sent home by school are of paramount importance. School nurses should be part of this process.	Thank you for your comments. Given the difference in the impact of IBS and the different approaches that may be required for the diagnosis and management of the condition in children, it is the recommendation of the NCC-NSC that separate guidance is produced. On this basis, children are not included in the scope. Guideline topic suggestions can be submitted to the Department of Health via the NICE website. http://www.nice.org.uk.

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Royal Liverpool Children's NHS Trust	2	General	The lower limit of 12 years for the guideline is arbitrary apart from possibly being the cut off age for eligibility for adult licensed drugs. This condition causes a very significant burden on children below 12 and on their families. Consideration should be given to withdrawing this age constraint.	Thank you for your comments. Given the difference in the impact of IBS and the different approaches that may be required for the diagnosis and management of the condition in children, it is the recommendation of the NCC-NSC that separate guidance is produced. On this basis, children are not included in the scope. Guideline topic suggestions can be submitted to the Department of Health via the NICE website. http://www.nice.org.uk.
Royal Liverpool Children's NHS Trust	3	General	The title on the scope document doesn't include children.	Thank you for your comments. Given the difference in the impact of IBS and the different approaches that may be required for the diagnosis and management of the condition in children, it is the recommendation of the NCC-NSC that separate guidance is produced. On this basis, children are not included in the scope. Guideline topic suggestions can be submitted to the Department of Health via the NICE website. http://www.nice.org.uk.
Royal Liverpool Children's NHS Trust	4	3g	The field of primary investigation for children is somewhat different in children than in adults. Endoscopic evaluation cannot be done in primary care and requires a general anaesthetic.	Thank you for your comments. Given the difference in the impact of IBS and the different approaches that may be required for the diagnosis and management of the condition in children, it is the recommendation of the NCC-NSC that separate guidance is produced. On this basis, children are not included in the scope. Guideline topic suggestions can be submitted to the Department of Health via the NICE website. http://www.nice.org.uk.
Royal Liverpool Children's NHS Trust	5	3g	Screening for coeliac disease should include tTG and an IgA level with advice to proceed to endoscopic biopsy in the event of an interpretable result and/or a low IgA level.	Thank you.
Royal Liverpool Children's NHS Trust	6	3g	Inflammatory markers such as ESR, CRP and platelets should be considered in the screening tests.	Thank you.
Royal Liverpool Children's NHS Trust	7	3g	When considering the role of investigations it is valid to consider the reassurance which investigations provide for patients and families- this is often intangible and not well covered in the literature.	Thank you for your comments. Given the difference in the impact of IBS and the different approaches that may be required for the diagnosis and management of the condition in children, it is the recommendation of the NCC-NSC that separate guidance is produced. On this basis, children are

SH organisation	No.	Section no.	Comments	Developers' response
				not included in the scope. Guideline topic suggestions can be submitted to the Department of Health via the NICE website. http://www.nice.org.uk.
Royal Liverpool Children's NHS Trust	8	4.3.2	It is important that newer medications such as the 5-HT agonists and antagonists are included. They may well have become mainstream by the time the guidelines are finalised. Consideration should be given to drugs in children and should emphasise the need for paediatric licensing due to become law. It is to be hoped that this will force the hand of drug companies etc to provide appropriate consideration for children.	Section 4.3.2 has been clarified Thank you for your comments. Given the difference in the impact of IBS and the different approaches that may be required for the diagnosis and management of the condition in children, it is the recommendation of the NCC-NSC that separate guidance is produced. On this basis, children are not included in the scope. Guideline topic suggestions can be submitted to the Department of Health via the NICE website. http://www.nice.org.uk.
Royal Liverpool Children's NHS Trust	9	4.1.1	Children are a special group- the Rome criteria maybe too rigorous and so lead to underestimation of incidence, the impact is very different to that of adult IBS in that they have very significant impacts on school attendance (? School performance and education achievement) and on anxiety within the family, psychological interventions may have a different focus especially as they must factor in the family.	Thank you for your comments. Given the difference in the impact of IBS and the different approaches that may be required for the diagnosis and management of the condition in children, it is the recommendation of the NCC-NSC that separate guidance is produced. On this basis, children are not included in the scope. Guideline topic suggestions can be submitted to the Department of Health via the NICE website. http://www.nice.org.uk.
Scottish Intercollegiate Guidelines Network (SIGN)			This organisation was approached but did not respond.	
Sheffield Children's Hospital NHS Trust	1	General	Thank you for the above that we received on 14 March 2006. This document relates to Irritable bowel syndrome in adults. It is therefore not directly applicable to paediatric services. Children do indeed suffer from irritable bowel syndrome but guidelines for management do not translate easily from the adult disease. It would be unhelpful if adult guidelines were intended to be applied to paediatric patients and I would suggest that any guidelines that are developed clearly indicate that a child with IBS may require a different approach in terms of diagnosis and management.	Thank you for your comments. Given the difference in the impact of IBS and the different approaches that may be required for the diagnosis and management of the condition in children, it is the recommendation of the NCC-NSC that separate guidance is produced. On this basis, children are not included in the scope. Guideline topic suggestions can be submitted to the Department of Health via the NICE website. http://www.nice.org.uk.
Sheffield Teaching Hospitals NHS Trust			This organisation was approached but did not respond.	

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Solvay Healthcare Limited			This organisation was approached but did not respond.	
South East Sheffield Primary Care Trust			This organisation was approached but did not respond.	
Staffordshire Moorlans Primary Care Trust			This organisation was approached but did not respond.	
The David Lewis Centre			This organisation was approached but did not respond.	
The Dudley Group of Hospitals NHS Trust			This organisation was approached but did not respond.	
The IBS Network	1	2a Background	Prevention is an inappropriate term.	Following consultation the Department of Health has agreed to remove prevention from the remit.
The IBS Network	2	3a	Rome 2 may be inadequate and out of date.	The guideline will look at different diagnostic methods of which Rome II is one, paragraph 3a has been revised to reflect this.
The IBS Network	3	3c	Over riding cause- Irritation of sensory nerve endings in bowel.	Thank you for your comment. We welcome the submission of evidence. Stakeholders are encouraged to submit relevant research evidence as described in The guideline development Process-An Overview for Stakeholders, the Public and the NHS (pg iv).
The IBS Network	4	3c	Colonic flora abnormal – not proven?	Thank you for your comment. We welcome the submission of evidence Stakeholders are encouraged to submit relevant research evidence as described in The guideline development Process-An Overview for Stakeholders, the Public and the NHS (pg iv).
The IBS Network	5	3d	Children – common cause of ab pain but then excluded.	Thank you for your comments. Given the difference in the impact of IBS and the different approaches that may be required for the diagnosis and management of the condition in children, it is the recommendation of the NCC-NSC that separate guidance is produced. On this basis, children are not included in the scope. Guideline topic suggestions can be submitted to the Department of Health via the NICE website. http://www.nice.org.uk.
The IBS Network	6	3e	Ass. Non-colonic probs include gallbladder and stomach.	This point has been included in 3e.

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The IBS Network	7	3f	Change in bowel habit over 40 need referring.	Thank you this point has been included.
The IBS Network	8	3h	Male or female surgery – proof??	Thank you for your comment. The paragraph describes the increased incidence of abdominal or pelvic surgery in IBS. The cause of the increased incidence has not been established.
The IBS Network	9	3i	Effective self management see IBS Network. Programme.	Thank you for your comment. Stakeholders are encouraged to submit relevant research evidence as described in The guideline development Process-An Overview for Stakeholders, the Public and the NHS (pg iv). Stakeholders are also encouraged to submit existing guidelines.
The IBS Network	10	4.1.1a	Why exclude children under 12.	Thank you for your comments. Given the difference in the impact of IBS and the different approaches that may be required for the diagnosis and management of the condition in children, it is the recommendation of the NCC-NSC that separate guidance is produced. On this basis, children are not included in the scope. Guideline topic suggestions can be submitted to the Department of Health via the NICE website. http://www.nice.org.uk.
The IBS Network	11	4.1.1.b	Special group menopausal women, gall bladder, students.	Thank you for your comment. These groups are included in the patient populations covered in the scope.
The IBS Network	12	4.1.2a	Other disorders need to be considered alongside IBS.	The guideline will deal exclusively with IBS and will not cover other disorders.
The IBS Network	13	4.1.2 b	Younger children need guidelines for this group too.	Thank you for your comments. Given the difference in the impact of IBS and the different approaches that may be required for the diagnosis and management of the condition in children, it is the recommendation of the NCC-NSC that separate guidance is produced. On this basis, children are not included in the scope. Guideline topic suggestions can be submitted to the Department of Health via the NICE website. http://www.nice.org.uk.
The IBS Network	14	4.3.2a	New drugs need to be considered on case by case basis - 5HT etc particularly when available in other countries.	Thank you for your comment. Section 4.3.2 has been clarified.

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The IBS Network	15	Appendix	Difficulty of diagnosis eg misdiagnosis endometriosis,ovarian cancer. And use of word prevention.	Thank you for your comment. Differential diagnoses will be covered in the guideline. Following consultation the Department of Health has agreed to remove prevention from the remit.
The National Pharmaceutical Association			This organisation was approached but did not respond.	
The Royal College of Surgeons Edinburgh			This organisation was approached but did not respond.	
The Royal Society of Medicine			This organisation was approached but did not respond.	
The Survivors Trust			This organisation was approached but did not respond.	
University of Birmingham, Department of Primary Care and General Practice		3b	The scope document suggested that prevalence may be in excess of 10-20% as many patients do not seek medical advice. We would like to draw your attention to the fact that community prevalence work in the UK has been conducted and does not suggest figure this high. (Wilson S et al BJGP 2004).	The guideline will review the evidence to support this comment. Stakeholders are encouraged to submit relevant research evidence as described in The guideline development Process-An Overview for Stakeholders, the Public and the NHS (pg iv).
University of Birmingham	1	3i and 4.2	We would encourage recognition of the fact that IBS may require long-term follow-up even where investigation and treatment options have been exhausted. Reassurance provided by investigation and being advised to self-manage symptoms means many patients live for years if not decades without further follow-up. These patients may be less likely to consult with symptoms which later develop as they attribute these to their IBS. There may therefore be greater risk that more significant disease which subsequently develops in these individuals may be missed or not presented to the GP.	Thank you for your comment. This point has been incorporated into the scope in section3a.
University of Birmingham	2	4.3.1	Whilst ROME II is criticised for being a professional rather than patient-led definition, it has been shown that patients meeting the ROME II criteria have worse quality of life than those with IBS symptoms who do not meet criteria (Wilson S et al BJGP 2004) so may be useful in terms of appropriate resource allocation.	Thank you for your comment. The guideline will look at different diagnostic methods of which Rome II is one, paragraph 3a has been revised to reflect this.

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University of Birmingham	3	4.3	We note that the scope document treats as a single diagnosis. The differing presentations and symptom profiles of patients need to be considered throughout the guideline development. Clinical management will inevitably be directed by presenting symptom profile at the symptom level, but different symptom types may have differing prognoses which may also assist in determining how rigorous investigation and treatment should be. We would suggest including the 3 common profiles; diarrhoea predominant, constipation predominant and alternating symptoms as an initial consideration.	The guideline will focus on the patient journey, which usually starts in primary care. It will cover the different symptom profiles addressing relevant investigations and treatments in whichever setting these are performed. The scope has been re-worded to reflect this point.
Welsh Assembly Government	1		Thank you for giving the Welsh Assembly Government the opportunity to comment on the above. We are content with the technical detail of the evidence supporting the provisional recommendations and have no further comments to make at this stage.	Thank you for your response.
Welsh Scientific Advisory Committee (WSAC)			This organisation was approached but did not respond.	
Whipps Cross University Hospital NHS Trust			This organisation was approached but did not respond.	