## National Institute for Health and Clinical Excellence

## Irritable Bowel Syndrome – Stakeholder consultation comments & Developers responses

Туре	Stakeholder	N O	Docu ment	Section number	Comments	Developer's Response. Please respond to all comments
SH	Addenbrooke's NHS Trust				This organisation was approached but did not respond.	
SH	Alizyme Therapeutics Ltd				This organisation was approached but did not respond.	
SH	Amgen UK Ltd				This organisation was approached but did not respond.	
SH	Association for Clinical Biochemistry				This organisation was approached but did not respond.	
SH	Association for Continence Advice				This organisation was approached but did not respond.	
SH	Association of Child Psychotherapists				This organisation was approached but did not respond.	
SH	Association of Coloproctology of Great Britain and Ireland				This organisation was approached but did not respond.	
SH	Association of Psychoanalytic Psychotherapy in the NHS				This organisation was approached but did not respond.	
SH	Barnsley Hospital NHS Foundation Trust				This organisation was approached but did not respond.	
SH	Barnsley PCT				This organisation was approached but did not respond.	
SH	Bedfordshire PCT				This organisation was approached but did not respond.	
SH	BHF Health Promotion Research Group				This organisation was approached but did not respond.	
SH	Boehringer Ingelheim Ltd				This organisation was approached but did not respond.	
SH	Breakspear Medical Group Ltd				This organisation was approached but did not respond.	
SH	Bristol PCT				This organisation was approached but did not respond.	
SH	British Association for Behavioural & Cognitive Psychotherapies (BABCP)				This organisation was approached but did not respond.	
SH	British Association for Counselling and Psychotherapy (BACP)	1	Full	Glossary	We note that there is no definition for cognitive behavioural therapy or counselling. Definitions for both terms need to be included in the glossary.	Thank you for your comment.
SH	British Association for Counselling and	2	Full	9.8	In relation to the following 'Thirdly, the GDG took into consideration the need to give people with IBS and their	Thank you for your comment. The generic term used is

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	Psychotherapy (BACP)				primary care clinician a choice in which behavioural therapy was most appropriate for them, and what might be available locally'. The behavioural therapies noted are primarily psychological therapies and not simply behavioural therapies.	psychological therapies.
SH	British Association for Counselling and Psychotherapy (BACP)	3	Full	9.8	In relation to the following 'The GDG considered CBT, hypnotherapy and psychotherapy, as a group of similar, but distinct therapies when making recommendations'. Hypnotherapy is not the same category of intervention as CBT and psychotherapy. It is not regarded as a psychobiological therapy by BACP and this draft guideline appears to indicate that it is. We are also confused about the reference to CBT and psychotherapy. CBT is one form of psychological therapy; psychotherapy is an umbrella term that covers a very wide range of psychological therapies including CBT. We would also question the absence of any reference to counselling approaches, as counselling and psychotherapy are seen by many as interchangeable.	Thank you for your comment. The generic term used is psychological therapies. The term counselling was not included as there were no trials which investigated counselling as an active treatment.
SH	British Association for Counselling and Psychotherapy (BACP)	4	Full	9.8	The recommendation on page 460 states that primary care clinicians should consider referring for 'behavioural therapies' and then in brackets includes cognitive behavioural therapy, hypnotherapy and psychological therapy. However as cognitive behavioural therapy is a psychological therapy, behavioural therapy needs to be replaced by 'psychological therapies'.	Thank you for your comment. The generic term used is psychological therapies.
SH	British Dietetic Association	1	Full	General	Thank you for giving The British Dietetic Association the opportunity to comment on this guidance.	Thank you for your comment
SH	British Dietetic Association	2	Full	2 Section 7	Paragraph on Dietary Fibre – perhaps further explanation on the difference between insoluble and soluble fibre would be helpful and the effect they may have in the gut. e.g: Constituents of dietary fibre have varying effects in the gut and can be adjusted according to specific IBS	Thank you for your comment. Further detail has been added to the fibre section.

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					symptoms. Soluble fibres form a gel when they absorb fluid in the gut and can help to soften the stool. Insoluble fibres increase stool bulk and reduce intestinal transit time. Both are fermented to varying degrees by gut microflora and may contribute to symptoms of wind and bloating. Refer to suitable dietary information giving more detail on foods containing soluble/insoluble fibre?	
SH	British Dietetic Association	3	Full	2 Section 7	Paragraph on wheat – ( consumption is often associated with increased symptoms) ADD IN: which may be due to the content of fibre, fructans or resistant starch.	Thank you for your comment. Amended as suggested.
SH	British Dietetic Association	4	Full	2 Section 7	Paragraph on Resistant Starches – (People with IBS), ADD IN: particularly symptoms of wind and bloating, (may benefit from)	Thank you for your comment. Amended as suggested.
SH	British Dietetic Association	5	Full	2 Section 7	Second paragraph on Lactose – (exclusion needs careful monitoring due to)ADD IN: the risk of causing (nutritional inadequacies)	Thank you for your suggestion
SH	British Dietetic Association	6	Full	2 Section 7	<ul> <li>Paragraph on Fructose –</li> <li>Suggest changing order of sentences – move first sentence (Fructose intake) to beginning of second paragraph.</li> <li>(in the small bowel can lead to colonic fermentation) – ADD IN: causing diarrhoea and wind and bloating.</li> </ul>	Thank you for your suggestion
SH	British Dietetic Association	7	NICE	Introducti on P4	Guidelines will assume prescribers will use a drugs summary to inform decisions' - why assume this, surely more goes into decision making process	Standard NICE commentary
SH	British Dietetic Association		NICE	P6	Why not ask about episodes gastroenteritis?	Thank you for your comment The GDG did not feel that this was necessary and outside of the scope
SH	British Dietetic Association	9	NICE	P7	On a practical basis primary care clinicians e.g. GP/practice nurse etc ability to review fibre in diet is limited/meaningless?	The GDG disagree and see this as important symptom management. Specialist

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						Dietician advice is suggested within the guideline when appropriate.
SH	British Dietetic Association		NICE	P9	20% experiencing incontinenceasked directly' - this should be supported by data on frequency of incontinence in proven IBS as otherwise implies high frequency (which I thought was not the case). Would need to be proven IBS otherwise surely you are counting undiagnosed IBD?	IBS is a disease spectrum, IBS – C (Constipation), IBS – D (Diarrhoea) and IBS – mixed. Data suggests that many people have high frequency of bowel motions, and in particular when diagnosed with IBS-D
SH	British Dietetic Association	11	NICE	P10	PCOS and IBS exacerbations - to elucidate?	Thank you for your suggestion
SH	British Dietetic Association	12	NICE	1.2.1.4	Use of caffeine in constipation predominant IBS??? no basis for giving out blanket ban on caffeine (and realistic???)	Thank you for your suggestion, see full guideline Section 7 Diet and Lifestyle.
SH	British Dietetic Association	13	NICE	1.2.1.4	Alcohol - zero or within sensible drinking limits NB in my rather limited clinical experience on this even with a consistent reaction to alcohol some clients are not willing to give up alcohol but continuing to seek other answers/persisting with appointments	Thank you for your comment
SH	British Dietetic Association	14	NICE	1.2.1.4	limiting fruit (why? constipation etc)	Thank you for your comment. As a soluble fibre, patients should manage their daily intake proportionally including fruit and vegetables as too much fruit may exacerbate symptoms.
SH	British Dietetic Association	15	NICE	1.2.1.7	no consideration of foods already being excluded by patient	This would be reviewed by the Dietician, see full guideline
SH	British Dietetic Association		NICE	1.2.1.4	only using Bristol stool chart when assessing drug efficacy - why not earlier in assessment process?	Thank you for your comment, the Bristol Stool Chart features in other places as suggested in the full guideline eg. managing medication. Also included as an appendix in NICE version.
SH	British Dietetic Association	17	NICE	4	section 4 doesn't seem to cover dietary	Thank you for your comment

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					recommendations but does others - any reason?	
SH	British Dietetic Association	18	NICE	1.2.1.4	Reduce intake of 'resistant starch', ADD IN: particularly for symptoms of wind and bloating, which is	Thank you for your suggestion
SH	British Dietetic Association	19	NICE	1.2.1.4	People with wind and bloating REPLACE WITH: Increasing intake of oats (such as) and linseeds (up to 1tbsp per day) may be helpful for symptoms of constipation, wind and bloating.	Thank you for your suggestion
SH	British Dietetic Association		NICE	1.2.1.5	this should be soluble fibre (such as ispaghula powder, methylcellulose or sterculia)	Thank you for your suggestion
SH	British Dietetic Association		Full	General	Does there need to be a definition of what an appropriate qualified Nutritionist or is this not possible?	Thank you for your comment and it was the feeling by specialist dietetics input within the GDG that this was the right phrasing to use
SH	British Dietetic Association	22	Full	P127	Is it worth moving the resistant starch section to near the colonic fermentation section as it is similar? Does there need to be an explanation of why resistance starch causes these symptoms?	Thank you for your comment
SH	British Dietetic Association	23	Full	P130	There is a typo on pg 130 line 14 of probiotic	Thank you for your suggestion. Amended
SH	British Dietetic Association	24	Full	General	Is there scope for more practical dietary advice for GP's, e.g. how to advise to reduce fibre in the diet or is it not included in the NICE remit? Will GP's be directed to a dietitian or the BDA factsheets or gastro sheets?	This is outside the scope of the guideline however your suggestion has been passed on to the NICE implementation team.
SH	British Dietetic Association	25	Full	P127	Diet and Lifestyle recommendation re commencing an elimination diet suggests advice be obtained from a registered dietitian or an appropriately qualified nutritionist,	Thank you for your comment and it was the feeling by specialist dietetics input within the GDG that this was the right phrasing to use
					'Appropriately qualified nutritionist' needs specific definition as the only recognized qualification for the latter is that of a Public Health Nutritionist, unlike that of 'dietitian' which is a recognized profession with a protected title regulated by The Health Professions	

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					Council.	
SH	British Geriatrics Society - Gastro-enterology and Nutrition Special Interest Group				This organisation was approached but did not respond.	
SH	British Homeopathic Association	1	Nice	general	GPs trained in homeopathy, as well as the NHS Homeopathic Hospitals, frequently treat patients with IBS. The majority of such patients have reported symptom improvement. Research recommendations should reflect these points.	There are two trials in homeopathy, both conducted about 30 years ago and reported in German and nothing has been done since. Only randomised trials were to be considered for this review and the absence of further studies suggests no need to carry out a review.
SH	British National Formulary (BNF)				This organisation was approached but did not respond.	
SH	British Nuclear Medicine Society	1	Full	general	This is 512 page document concentrating on diagnosis and treatment of IBS in adults (18 years and over). This is comprehensive review of the topic, scrutinising the evidence for different pathways for diagnosis and the efficacy and cost effectiveness of treatment and diagnostic pathways. The first 125 pages deal with diagnosis of IBS.	Thank you for your comment. Referral to secondary care can be found in the patient algorithm and in section 6 of the full guideline
					Two approaches have been considered for diagnosis of IBS. Diagnosis by exclusion (by performing various invasive and non-invasive tests) is deemed to be expensive and un-productive. A "positive diagnosis" approach is recommended. Clinical history criteria is used for positive diagnosis of IBS, adopted form published data from several groups (ROME I, ROME II, Manning, etc criteria) and specifies "red flag" symptoms and signs which would prompt secondary referral. The aim is to treat patients in the primary care setting, with positive diagnosis from history and minimal	

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					<ul> <li>investigations. The secondary referral is made only if one of the "red flag" criteria is present. There are six red flag criteria: <ol> <li>Unintentional and unexplained weight loss</li> <li>rectal bleeding</li> <li>family history of bowel cancer</li> <li>anaemia</li> <li>abdominal masses</li> <li>rectal masses</li> </ol> </li> <li>The only relevance to Nuclear Medicine is exclusion of Urea Breath Test in work up of patients for IBS in primary care (which is performed if diagnosis by exclusion is used) and thus is not recommended. Bowel transit studies have been mentioned as only part of secondary referral investigation, and not in the primary care. There is no studies support or at usefulness of transit studies in IBS patients.</li> </ul> Majority of the document is about the treatment (usually major symptoms only) in IBS. There is no imaging involved in this section. The document is comprehensive and gives recommendations based on literature. The guideline has no direct impact on imaging, as it plays little role on routine management of IBS patients. My only comment is that the "red flag" criteria are mentioned in the initial diagnosis of IBS, however it is not specifically mentioned that the emergence of any of the "red flag" criteria during the management of these patients (after initial diagnosis) should prompt referral for secondary care centres, and further investigation. In view of the difficult diagnosis and subjective criteria I am sure the guidelines will be reviewed regularly as the	Thank you for your comment 'the emergence of any of the "red flag" criteria during the management of these patients (after initial diagnosis) should prompt referral for secondary care centres, and further investigation.' Has been added

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					understanding of the disease is improves.	to the follow up section.
SH	British Psychological Society, The				This organisation was approached but did not respond.	
SH	British Society of Gastroenterology	1	Full	General	I congratulate the GDG on producing a definitively patient-oriented journey through the diagnostic and management process in primary care.	Thank you for your comment
SH	British Society of Gastroenterology	2	Full	General	I am concerned at "considering" the diagnosis of IBS after just 6 months of symptoms; I would argue in favour of a longer period (? 24 months) in an attempt to reduce the number of patients who have an organic disease missed.	This time period for secondary care is reasonable, but was absolutely rejected by the GDG, and in particular by patient representatives and primary care clinicians.
SH	British Society of Gastroenterology	3	Full	General	Would the GDG consider including the presence of night-time symptoms as a helpful feature in making a positive diagnosis of IBS?	Thank you for your suggestion the GDG considered this point felt that this was not clear cut and chose not to include night time symptoms.
SH	British Society of Gastroenterology	4	Full	General	What - if any - do the GDG feel is the role of other health-care advice in the primary care setting for patients with IBS (pharmacists, patient groups)?	Thank you for your comment. The GDG feel that other health care advice is useful when given by those with appropriate training and experience in IBS
SH	British Society of Gastroenterology	5	Full	General	Whilst applauding the guidelines emphasis on simplifying the dietary beliefs that some patients have, I am concerned about the level of certainty awarded to certain foodstuffs like oats. Whilst understanding the need to use consensus where evidence is slight, I am concerned at the possible undue weight given to some evidence such as the oats literature.	Thank you for your comment. We have added to the GDG discussion and evidence to recommendations sections of the Fibre review.(pg 166-7 full guideline). GDG consensus was that an example should be given of a food high in soluble fibre, as well as citing the supplements used in the RCTs. GDG consensus was that oats should be added to the recommendation as an

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						example only.
SH	British Society of Gastroenterology	6	Full	General	In terms of evidence, it could be argued that the evidence in favour of SSRIs is stronger than that for tricyclic antidepressants (especially when considering some of the early, lower quality studies in the latter group).	Thank you for your comment. There were also methodological limitations with the SSRI trials and the effect on pain was more significant for TCAs. The GDG considered the latter to be a more important intervention.
SH	British Society of Gastroenterology	7	Full	General	I am not certain that a standard length GP consultation will be sufficient to allow sufficient time to make a diagnosis and give the necessary empathic advice advocated in the guidance. This is potentially my most major concern in terms of making the guideline applicable in the real world setting.	Thank you for your comment. The time taken to make a positive diagnosis using the criteria was tested by the GDG during the guideline development and found to be sufficient. However this is a primary focus for implementation with primary care clinicians.
SH	BUPA				This organisation was approached but did not respond.	
SH	Calderdale PCT				This organisation was approached but did not respond.	
SH	Cardiff and Vale NHS Trust				This organisation was approached but did not respond.	
SH	CIS'ters				This organisation was approached but did not respond.	
SH	Coeliac UK				This organisation was approached but did not respond.	
SH	Coloplast Limited				This organisation was approached but did not respond.	
SH	Commission for Social Care Inspection				This organisation was approached but did not respond.	
SH	Connecting for Health				This organisation was approached but did not respond.	
SH	Continence Advisory Service				This organisation was approached but did not respond.	
SH	Continence Foundation				This organisation was approached but did not respond.	
SH	Conwy & Denbighshire Acute Trust				This organisation was approached but did not respond.	
SH	Counsellors and Psychotherapists in Primary Care				This organisation was approached but did not respond.	
SH	Department of				This organisation was approached but did not respond.	

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	Gastroenterology					
SH	Department of Health, Social Security and Public Safety of Northern Ireland				This organisation was approached but did not respond.	
SH	Derbyshire Mental Health Services NHS Trust				This organisation was approached but did not respond.	
SH	Derbyshire Mental Health Trust				This organisation was approached but did not respond.	
SH	Dudley Group of Hospitals NHS Trust				This organisation was approached but did not respond.	
SH	Ferring Pharmaceuticals Ltd	1	NICE Full Version	1.2.1.6	Taking into account the detailed discussions in relation to probiotics and the management of IBS presented in this document by the GDG and their discussion as follows: Page 130 Line 17 –"It should be noted that many available probiotics have not had health benefits identified or been scientifically proven to be beneficial to the host (Reid, 2000)" Page 187 Lines 1 –20 - GDG Discussion And more specifically under Evidence Statements point 2 P187 Lines 26-28 "2. There is good evidence to show a significant difference in global symptom score for combined probiotics compared with placebo, favouring probiotics, but no significant difference for single probiotics as a group in people with IBS."	Thank you for your comment, amended.
					RECOMMENDATION	
					Primary care clinicians should not discourage people with IBS from trying specific probiotic products. If people with IBS choose to do this, it should be for at least 4 weeks, and they should monitor their effect. The probiotic should be taken at the dose recommended by	

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					the manufacturer. Could be amended to more accurately reflect the conclusions of the GDG, and to protect the IBS sufferer from unnecessary experimentation, to the following: Primary care clinicians should not discourage people with IBS from trying specific probiotics for which there is clinical evidence from trials to demonstrate potential benefits, and taking into consideration the specific symptoms associated with each patient. Such probiotics are typically made from combinations of strains and are presented in a concentrated form. If people with IBS chose to do this, it should be for at least 4 weeks, and they should monitor their effect. The probiotic should be taken at the dose recommended by the manufacturer, taking into account available evidence of proven	
SH	Ferring Pharmaceuticals Ltd	2	Full	2 7 Diet and Lifestyle Line 37- 38	efficacy. Note a typographical error lists "good bacteria" twice in the same sentence.	Thank you for your comment, amended.
SH	Health and Safety Executive				This organisation was approached but did not respond.	
SH	Healthcare Commission				This organisation was approached but did not respond.	
SH	Heart of England Acute Trust	1	Full	General	The guideline has apparently shunted Secondary Care (Specialist Consultation). It seems to have placed the complete management in Primary Care without the opportunity for second opinion and management of difficult cases.	Thank you for your comment, this guideline is about diagnosis and management in Primary Care, where most patients can be managed. If intractable symptoms persist, or in the presence of red flags, secondary care referral is suggested.

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SH	Heart of England Acute Trust	2	Full	General	Whilst we agree in principle with the idea of positive diagnosis of IBS, the symptoms are not pathognomonic hence some additional information will be necessary for this diagnosis to be confirmed.	Thank you for your comment, this highlighted the importance of taking a detailed patient history.
SH	Heart of England Acute Trust	3	Full	P257- Line 9	Statement refers to PEG versus Lactulose whereas on Line 12 & 13 the comparison is now between PEG and placebo. This needs correction.	Thank you for your comment. Amended.
SH	Incontact	1	Full	General	We welcome a clinical guideline on IBS that focuses on self-help and treatment in primary care. However we have concerns that the approach to diagnosis will increase the number of people wrongly diagnosed as having IBS. We also have doubts that GP's have the time to spend on diagnosis. It usually takes a great deal of time (even after tests have ruled out any organic causes for the symptoms) to inform patients empathically that they have IBS and formulate a care plan to try to alleviate symptoms.	Thank you for your comment. This is not supported by the evidence.
					While the scope excludes people with co-morbidities, it is vital they are signposted to appropriate care. The possible additional needs of disabled people must be addressed when they present with symptoms suggestive of IBS. There is little or no guidance on how to avoid diagnostic overshadowing particularly in those with other long term conditions including learning disabilities and mental health problems. Stating that it is outside the scope will not lead to equality of access to appropriate care.	Thank you, a sentence has been added re referral of those with co-morbidities/ learning disabilities etc
			NICE		There appears to be little guidance as to who needs referral to secondary care other than cancer. Failure for symptoms to improve may be an indication that another GI condition is present. Although other investigations are not needed for the diagnosis of IBS, they are needed to exclude other conditions such as IBD.	Inflammatory Bowel Disease has been added to the algorithm

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					Others may be better managed in secondary care by a specialised gastrointestinal multidisciplinary team. It is vital that other coping skills not just diet and stress avoidance are given in a recommendation so that it appears in the UNG version. People with IBS need information on how they can cope with everyday life. Those with frequent loose stools and/or incontinence need advice on journey planning, use and access to toilets when out and about. There is no mention of carrying a card which tells others that the person has a medical condition and requires urgent access to a loo that can help jump long queues, or enable use of staff toilets in businesses without public toilets. There	Your suggestion has been passed on to the NICE implementation team.
SH	Incontact	2	NICE	р5	appears to be no information on support organisations. Not all people with IBS will consider themselves as patient's, suggest "Person" rather than "Patient"	Thank you for your comment. Amended.
					Centred Care as in Full version. HCP should be aware of both the physical and emotional impact that IBS may have on the person and their family. Written information may be inappropriate for some people. Alternative formats should be available. Special consideration and specific strategies are needed to meet the information and advice needs of groups less likely to seek help. Information by itself is not always enough: people should be offered one to one support in understanding	
			Full	P32	and interpreting information and what it means for them as individuals. It would be helpful to include more from 2.1 in the NICE version.	
SH	Incontact	3	NICE	1.1	The clinician having a "feel" for multiple features of IBS does not always aid correct diagnosis We have concerns that those with other conditions but some of the features of IBS will be misdiagnosed. A normal	Thank you for your comment. Testing of the diagnostic criteria by the GDG proved that

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					length GP appointment of 10 minutes, only allows 5- 7minutes for examination, discussion and possible diagnosis. We cannot see this being adequate.	diagnosis within the time frame is possible. See Full guideline section 6.
					Advice and reference to the faecal incontinence guideline is needed for the 20 % of people with IBS who present or admit to having faecal incontinence.	Referral to faecal incontinence guideline included
SH	Incontact	4	NICE	1.1.1.1	These are non-specific gastrointestinal symptoms but hopefully they will not be dismissed as unimportant for 6 months. This does not help those people whose symptoms are due to bowel cancer IBD, coeliac disease or diverticulitis. They may fail to promptly diagnosed and referred to secondary care for further essential tests and investigations.	Thank you for your comment. Any red flag symptoms would be considered for immediate referral as would symptoms suggestive of other GI disorders.
SH	Incontact	5	NICE	1.1.1.3	People with bladder symptoms and or backache may not have these conditions taken seriously if they also have the other symptoms you mention. Some have both IBS and urge/stress urinary incontinence or overactive bladder syndrome. Bladder and bowel symptoms (especially altered stool passage) are also associated with prolapsed intervertebral disc or other spinal condition, not necessarily presenting acutely. It is vital that it is not assumed that all symptoms are due to IBS and people receive appropriate treatment/referral for bladder or suspected spinal conditions.	Thank you for your comment. See full guideline section 6
SH	Incontact	6	NICE	1.1.2.1	We are concerned that due to 1.1.1.1 that these tests may be delayed for 6 months. In suggesting that sigmoidoscopy, colonoscopy and barium enema should not be used in the normal diagnostic process for IBS, other bowel diseases that cause very similar symptoms to the extent that only visualisation is effective in finally making an accurate differential diagnosis may not be investigated. While these tests are embarrassing and uncomfortable to patients, they often give piece of mind	Thank you for your comment. Any red flag symptoms would be considered for immediate referral/investigation as would symptoms suggestive of other GI disorders.

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					to those with IBS. We know of a number of cases where long-standing (5 to 10 years) diverticular disease was labelled IBS until an acute attack of diverticulitis was visualised and correctly diagnosed by CT or MRI scan and responded to more appropriate treatment.	
SH	Incontact	7	NICE FULL	1.2.1.3	There is little evidence to support increased physical activity in IBS. It is important that any recommendation takes the needs of those with disabilities into consideration. We accept that most people's general health benefits from partaking in physical activity	Thank you for your comment
SH	Incontact	8	NICE FULL	1.2.15	The Guidance describes 2 distinct types of IBS. The fibre guidance appears to be more applicable to diarrhoea dominant. IBS, rather than those with constipation, which may be made worse by antidepressants. There is great variation in how much fibre individual patients tolerate. We however agree that most tolerate soluble better rather than insoluble forms.	Thank you for your comment
SH	Incontact	9	NICE/F ULL	1.2.1.8	We welcome this recommendation. It is vital people with IBS have access to sound advice from registered dietitians, preferably one who specialise in gastroenterology	
SH	Incontact	10	NICE/F ULL	12.2.5- 1.2.2.7	We have concerns over the general recommendation for off licence use even as a second line therapy for antidepressants in IBS on minimal evidence unless the patient has co-existing depression. The side effects of tricyclics are well known and documented and occur even in low doses. We accept they are useful in some patients where pain is a major symptom(in the absence of pre-existing constipation) but until further research as in 4.2, is carried out they must be prescribed on an individual basis with the patient aware that their use in IBS for pain rather than depression is unlicensed. Trials should focus on identifying which people with IBS are likely to benefit most, as well as dosage. It is important that any trial of these drugs is carried out and closely	Thank you for your comment. The GDG accept that the use of low dose antidepressant therapy for pain management is off licence and have included a research recommendation to increase the evidence base.

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					monitored by a multidisciplinary team, unlikely to be found solely in primary care.	
SH	Institute of biomedical Science				This organisation was approached but did not respond.	
SH	Institute of Psychiatry				This organisation was approached but did not respond.	
SH	JOHNSON & JOHNSON CONSUMER SERVICES EAME LTD				This organisation was approached but did not respond.	
SH	Kimal Plc	1			This organisation was approached but did not respond.	
SH	Leeds PCT	1			This organisation was approached but did not respond.	
SH	Liverpool PCT				This organisation was approached but did not respond.	
SH	Medicines and Healthcare Products Regulatory Agency (MHRA)				This organisation was approached but did not respond.	
SH	Mental Health Act Commission				This organisation was approached but did not respond.	
SH	National Association for Colitis and Chron's Disease (NACC)	1	NICE	General Section 1.1	Overall NACC and the Medical Advisers we have consulted believe this to be a very good document which should if properly implemented significantly improve diagnosis and management of IBS in primary care. We are focusing our comment on the proposals for diagnosis and in general terms feel that these will appropriately establish a more systematic approach to diagnosing IBS relying on the less intrusive investigations and clinical judgement. This more systematic approach has the potential to improve the diagnosis of lower GI conditions in general.	Thank you for your comment.
					However, we do feel that inadequate attention has been given in the guidance to the differential diagnosis of Inflammatory Bowel Disease (IBD), particularly in relation to younger people. If left unchanged we feel that this would be a regrettable missed opportunity to improve the early diagnosis of IBD.	IBD has been specifically included in the red flags and on the algorithm.

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					Significant attention has been paid to the differential diagnosis of bowel cancer with the 'red flag' signs being explicitly stated both in the text and in the algorithm presented as Appendix C.	
					Similarly antibody testing for Coeliac disease is explicitly mentioned in both text and algorithm.	
					We feel strongly that, particularly for adults under 40 years of age, IBD should be explicitly included as a differential diagnosis with an alert indicator similar to the red flags for cancer.	
				After Section 1.1.2.1	We also feel that there should be a statement about referring people for further investigation if a patient diagnosed with IBS continues to present with general ill- health and with symptoms that might be indicative of IBD.	
				Section 1.1.2.2	We suggest an additional paragraph after 1.1.2.1 as follows: Particular attention should be paid to adults under 40 years of age who present with any combination of rectal bleeding, frequency, urgency, passage of mucus, raised CRP or a family history of IBD. These patients should be referred to secondary/tertiary care for investigation of possible IBD.	Addition to the algorithm to explain differential diagnosis including IBD-Crohns etc
				After Section 11.2.2	We would suggest an addition to para 1.1.2.2, where the text says: 'The following tests should not be done to confirm diagnosis in people who meet the diagnostic criteria,' (add) unless they also have signs indicative of possible inflammatory bowel disease as set out in the preceding paragraph.	

Туре	Stakeholder	N O	Docu ment	Section number	Comments	Developer's Response. Please respond to all comments
					Patients who have been diagnosed with IBS but who continue to present with general symptoms of ill-health, unexplained loss of appetite or loss of weight or other signs of IBD should be referred for further investigation.	See above
SH	National Association for Colitis and Chron's Disease (NACC)	2	NICE	Appendix C	We propose that the algorithm should have an additional box under the 'cancer 'red flags and before the box containing the words 'IBS Positive Diagnosis Criteria' to state the indicators for diagnosis of IBD and the instruction to refer to secondary/tertiary care.	Addition of IBD in algorithm to explain differential diagnosis
SH	National Association of British and Irish Millers				This organisation was approached but did not respond.	
SH	National Patient Safety Agency				This organisation was approached but did not respond.	
SH	National Pharmacy Association				This organisation was approached but did not respond.	
SH	National Phobics Society				This organisation was approached but did not respond.	
SH	National Public Health Service - Wales				This organisation was approached but did not respond.	
SH	National Treatment Agency for Substance Misuse				This organisation was approached but did not respond.	
SH	Newham University Hospital NHS Trust				This organisation was approached but did not respond.	
SH	NHS Clinical Knowledge Summaries service				This organisation was approached but did not respond.	
SH	NHS Direct				This organisation was approached but did not respond.	
SH	NHS Plus				This organisation was approached but did not respond.	
SH	NHS Quality Improvement Scotland				This organisation was approached but did not respond.	
SH	Norgine Ltd	1	NICE	General	It is notable throughout that the guideline does not distinguish specific subtypes of the condition. We believe that as definition of IBS subtype will fundamentally effect treatment, it is important to refer to the subtypes in diagnosis and management of IBS. Whilst it is true that the subtype may vary over time in an individual patient, management choices do depend on the predominant subtype at any given moment in	Thank you for your comments. See full version pg 32

Туре	Stakeholder	N O	Docu ment	Section number	Comments	Developer's Response. Please respond to all comments
					time.	
SH	Norgine Ltd	2	NICE	1.1	This section does not refer to the need to define the subtype of IBS of which the patient is complaining. The Rome III criteria define 4 subtypes of IBS: IBS with constipation (IBS-C), IBS with diarrhoea (IBS-D), IBS with mixed constipation and diarrhoea (IBS-M), and a fourth group (un-subtyped) for patients with symptoms which do not fit into the first 3 sub-classifications. As the treatment of IBS is symptomatic, we believe that it is important to define the primary sub-type in order to prescribe appropriate treatment for the symptoms experienced.	Thank you for your comments
SH	Norgine Ltd	3	NICE	1.1	The guideline states that patients commonly report, inter alia, 'rectal hypersensitivity'. This term would almost certainly not be a term patients would use when talking to a practitioner, and most primary care practitioners would not understand it either. If incomplete evacuation and urgency are the signs of 'rectal hypersensitivity' then the guidelines should refer to these signs alone, and omit reference to 'rectal hypersensitivity'.	Thank you for your comments. This term has been removed
SH	Norgine Ltd	4	NICE	1.1	It may assist clinicians in making a diagnosis of IBS to point out that patients may not only have gastrointestinal symptoms, they may also have non- gastrointestinal complaints e.g. urinary tract symptoms such as frequency, urgency and nocturia; backache; dyspareunia; tiredness and disturbed sleep, and that the presence of such symptoms may support the diagnosis of IBS.	See full guideline pg 95/96
SH	Norgine Ltd	5	NICE	1.1.2.2	In section 1.1.2.2 it should probably be added that the tests listed should not be done unless the patient has 'red flag' symptoms.	Thank you for your comments
SH	Norgine Ltd	6	NICE	1.2	This whole section on clinical management would be more helpful as a guideline if it referred to specific treatments recommended for each of the sub-types of	Thank you for your comments The management is based on the symptom profile and is

Туре	Stakeholder	N O	Docu ment	Section number	Comments	Developer's Response. Please respond to all comments
					IBS.	patient centred.
SH	Norgine Ltd	7	NICE	1.2	In section 1.2.1.4 the guidelines refer to 'resistant starch'. Practitioners may not be familiar with this term, and it may be a good idea to define what is meant by 'resistant starch'.	Thank you for your comments amended
SH	Norgine Ltd	8	NICE	1.2	Section 1.2.1.5 says that patients with IBS should be actively discouraged from taking insoluble fibre, but should instead take soluble fibre if an increase in fibre is advised. This advice could be more helpful if it included reference to the appropriateness or otherwise of increasing fibre according to the different diagnostic sub-types.	Thank you for your comments The fibre recommendation is a general recommendation which may be applicable to all people with IBS
SH	Norgine Ltd	9	NICE	1.2.2	We would support the recommendation to actively discourage patients from taking lactulose, as it is fermented in the large bowel to produce gas, which can aggravate bloating. We would also propose that stimulant laxatives like senna and bisacodyl should also be actively discouraged, as they can in themselves cause cramp-like abdominal pain which would not be desirable in patients who are already complaining of abdominal pain or discomfort as part of their condition.	Thank you for your comments.
SH	Norgine Ltd	10	NICE	1.2.3.1	It is not clear where the term 'refractory IBS' originates from. This term is not defined in the Rome criteria.	Refractory IBS defined in full version, pg 22 of the glossary
SH	Norgine Ltd	11	NICE	1.2.3.1	The recommendation that clinicians should consider referring patients for behavioural therapies if they have failed to respond to 'first-line' therapies after 12 months does seem very arbitrary. What is the evidence to support the 12 month proposal? One could argue that behavioural interventions which have been shown to be effective in at least a proportion of patients with IBS should be offered earlier than 12 months after diagnosis when patients have developed a 'refractory' condition. As many of these interventions are not funded by the NHS it would not adversely affect the cost to the NHS of treating IBS if these interventions were offered earlier in	Thank you for your comment

Туре	Stakeholder	N O	Docu ment	Section number	Comments	Developer's Response. Please respond to all comments
					the course of the illness.	
SH	Norgine Ltd	12	NICE	1.2.4	This section only refers to acupuncture and reflexology not being encouraged for patients with IBS. These statements may mislead a practitioner into thinking that other CAM therapies can be encouraged for patients with IBS. This section would be better if it stated that no CAM therapies have been shown to be effective in IBS, rather than saying that reflexology and acupuncture have been shown to be ineffective in treating IBS.	Thank you for your comments As not all CAM therapies were reviewed the guideline can only comment on therapies included in the guideline
SH	North Eastern Derbyshire PCT				This organisation was approached but did not respond.	
SH	Northwick Park and St Mark's Hospitals NHS Trust	Vick Park and St Mark's als NHS Trust           1         Full         General         Throughout the document therapies" is used synonor therapies". This is confusir "Psychological therapies" with the term, which covers, inter a psychodynamic etc psychological therapies", value approaches are mentioned psychotherapybut this is For instance Dr Stirling Moc Consultant Psychotherapis writes "In contrast to psychotherapis", behavioural therapies", Ch 37 in Wright P, Stern J and Pheliptical States	Throughout the document the term "Behavioural therapies" is used synonomously with "Psychological therapies". This is confusing and incorrect. "Psychological therapies" would be the correct umbrella term, which covers, inter alia behavioural, cognitive, psychodynamic etc psychotherapies. So, for instance on p. 369 of the full document, under the heading "Behavioural therapies", various psychotherapeutic approaches are mentioned including (p.371) "dynamic psychotherapybut this is NOT a behavioural therapy. For instance Dr Stirling Moorey, a well known Consultant Psychotherapist at the Maudsley hospital writes "In contrast to psychoanalytic approaches to therapy, behavioural therapy is far more structured and directive" (Moorey,S "Behavioural and cognitive psychotherapies", Ch 37 in Core Psychiatry ( edited by Wright P, Stern J and Phelan M (Elsevier, 2 <sup>nd</sup> ed, 2005)).	Thank you for your comments Terminology has been clarified.		
					So our recommendation is that throughout the documents-full nd summary-, wherever the term "Behavioural therapy/ies" is used, it needs to be replaced by the term "Psychological therapies" (except when referring explicitly to the particular modality of therapy i.e. behaviour therapy or CBT)	

Туре	Stakeholder	N O	Docu ment	Section number	Comments	Developer's Response. Please respond to all comments
SH	Northwick Park and St Mark's Hospitals NHS Trust	2	Full	p371	It is claimed that in Short term or focal dynamic therapy "attention is focussed on only one area of the person's experience". This is not entirely accurate. There is a focus, the therapy is time-limited, but attention cannot be literally on "one area only". Perhaps it is more accurate to talk about a focus.	Thank you for your comments
SH	Northwick Park and St Mark's Hospitals NHS Trust	3	Full	p393	Figures 12 and 13 and 14 : should graphs be labelled "favours antidepressants/ favours psychotherapy" rather than "treatment" and "control"?	Thank you for your comments
SH	Northwick Park and St Mark's Hospitals NHS Trust	4	Full	p395	Line 27 "The number" not "There"	Thank you for your comment. Amended
SH	Northwick Park and St Mark's Hospitals NHS Trust	5	Full	p398	Table 1: Cost offset£4.70, not \$4.70 ?	The cost offset was measured in UK£s but reported in US\$s in Creed 2003. We converted the figure back to UK£ and uplifted it to reflect current prices giving a cost offset applied in the model of £4.08. Table 1 will be amended to make this clearer
SH	Novartis Pharmaceuticals UK Ltd				This organisation was approached but did not respond.	
SH	Nutricia Ltd (UK)				This organisation was approached but did not respond.	
SH	Ovarian Cancer Action (joint comments with Pancreatic cancer UK)	1	Full	General	From Ovarian Cancer Action: We have only very recently become aware of this consultation and guidance development, and have significant concerns that it does not address the exclusion of ovarian cancer as a possible cause of symptoms. We have highlighted below the main recent developments in research and understanding that can inform your guidance development	Thank you for your comments Exclusion of ovarian cancer has been added to the algorithm and the guideline
					IBS is the most common diagnosis given to women who are subsequently shown to have ovarian cancer, and delays in getting a correct diagnosis contribute	

Туре	Stakeholder	N O	Docu ment	Section number	Comments	Developer's Response. Please respond to all comments
Туре	Stakeholder	-			significantly to the fact that England has the lowest survival rate in Europe (Eurocare4 study, 2007, Lancet). In the UK, around 75% of women with ovarian cancer are diagnosed once the condition has already spread. In general, ovarian cancer is a disease affecting women over the age of 40. Two thirds of cases are in women over the age of 50, and recent research by Barbara Goff et al (Cancer, 2007) identifies that the persistency and frequency of symptoms is of significant value in distinguishing between those women who have ovarian cancer, and those who have other conditions such as IBS. In particular, if a woman presents with one or more of the key symptoms being experienced more than 12 times a month, then ovarian cancer should be considered. Key symptoms include bloating/abdominal distention, pelvic/abdominal pain, difficulty eating/feeling full, urinary urgency and frequency. Development of an Ovarian Cancer Symptom Index: Possibilities for Earlier Detection." Published Dec. 11, 2006, in the online edition of Cancer. First author: Barbara A. Goff, MD, University of Washington School of Medicine. Given that IBS, according to the guidelines occurs mostly in women aged 20-30, and according to the	Please respond to all
					<ul> <li>Rome III criteria, and the Goff research, frequency of symptoms tends to be considerably less than for ovarian cancer we would suggest the following</li> <li>That women over 40, experiencing very frequent symptoms (more than 12 times in four weeks) of relatively recent onset have ovarian cancer</li> </ul>	
					<ul> <li>excluded as a potential diagnosis</li> <li>That patients are asked to disclose if they have</li> </ul>	

Туре	Stakeholder	N O	Docu ment	Section number	Comments	Developer's Response. Please respond to all comments
					a family history of ovarian cancer, in addition to the questions about bowel cancer, as one of the red flag questions That women are assessed not only for abdominal or rectal masses, but pelvic masses	
SH	Ovarian Cancer Action (joint comments with Pancreatic cancer UK)	2	Full	1.1.1.2	From Ovarian Cancer Action: We feel very strongly that the most recent evidence on symptoms of ovarian cancer (Goff et al, CANCER 2007) should be reviewed with a view to incorporating information within this section, as per the bullet points above.	Thank you for your comment
SH	Ovarian Cancer Action (joint comments with Pancreatic cancer UK)	3	NICE	Introducti on	<ul> <li>Patients subsequently found to have pancreatic cancer are also often misdiagnosed as having IBS. This should be covered in the guidelines not just colorectal cancer.</li> <li>Page 3 add "symptoms sometimes overlap with other gastrointestinal (GI) disorders such as non-ulcer dyspepsia, or with celiac disease or with cancers such as ovarian and pancreatic.</li> <li>Also add "Therefore , IBS diagnosis should be a consideration when an older person presents with unexplained abdominal symptoms after ruling out cancers such as ovarian and pancreas."</li> <li>Page 6 add "familial history of bowel cancer or other cancers eg pancreatic and ovarian or pancreatitis"</li> <li>After reference to NICE clinical guideline 27 add (IBS can be confused with pancreatic or ovarian cancer so these should be rules out before a diagnosis of IBS is given)</li> <li>Page 7 add "It should be noted, and can be used to support the diagnosis but could also be associated with cancer)</li> </ul>	Thank you for your comment. After discussion the GDG felt that the symptom profile for people with suspected pancreatic cancer would differentiate them from those with IBS. There was insufficient clinical evidence to recommend the routine use of ultrasound in patients who meet the IBS diagnostic criteria and who have no red flag symptoms, The recommendation does not prevent clinicians referring patients with suspected cancer for appropriate tests as specified in Clinical Guideline 27.

Туре	Stakeholder	N O	Docu ment	Section number	Comments	Developer's Response. Please respond to all comments
					I am concerned that you recommend that ultrasound is not done. Whilst this is insufficient to pick up small pancreatic cancer tumours for which CT scans are required ultrasound can pick up some larger tumours for which patients have been given misdiagnosis of IBS. It is not invasive and I am concerned that advising against its use will make the problems with diagnosis of pancreatic cancer even worse in the future.	
SH	Ovarian Cancer Action (joint comments with Pancreatic cancer UK)	4	NICE	1.1	"This distinguishes IBS from cancer-related pain/discomfort, which typically has a fixed site" Pancreatic cancer patients frequently report that the location of pain varies from day to day etc.	
					The Bristol Stool chart does not seem to include steattorhea ie pale floating stools etc (associated with fat malabsorption in pancreatic cancer patients), which should be ruled out before making a diagnosis of IBS [XXX]. This should be mentioned in the guidelines.	The Bristol stool chart is a pictorial guide to illustrate range of 'normal stools. It is not intended for use to describe complete range of stools that may indicate other conditions.
SH	Ovarian Cancer Action (joint comments with Pancreatic cancer UK)	5	NICE	1.1.1.2	Unfortunately "red flag" symptoms for pancreatic cancer are not well enough defined and improved NICE guidance is required. This section should include ovarian and pancreatic cancer not just colon cancer. Patients should be asked about family history of pancreatic and ovarian cancer, pancreatitis, also smoking habits, tested for late on-set diabetes [XXX], also a CA19-9 test could be done to help test for or rule out pancreatic cancer (See Fast Facts: Diseases of the Pancreas and Biliary Tract Neoptolemos and Bhutani ISBN 1-903734-74-6)	Thank you for your comments. Refer to NICE
					Some information on symptoms of pancreatic cancer are given in Holly et al 2004, "signs and symptoms of pancreatic cancer: A population based case-control	

Туре	Stakeholder	N O	Docu ment	Section number	Comments	Developer's Response. Please respond to all comments
					study in the San Fransisco Bay Area " Clinical gastroenterology and hepatology 2004, 2, 510-517 Gullo et al 2001 "Do early symptoms of pancreatic cancer exist that can allow an earlier diagnosis" Pancreas Vol22 2 210-213 Sorry haven't had time to do a full search of references to help improve your current "red flag" symptoms and differentiation of pancreatic cancer from IBS. This needs careful consideration.	Refer to GDG and NICE
SH	Ovarian Cancer Action (joint comments with Pancreatic cancer UK)	6	Full	General	<ul> <li>[XXX] says:</li> <li>"The GL aims are OBJECTIVES</li> <li>5 1. To determine the effectiveness of diagnostic criteria for people with IBS.</li> <li>6 2. To determine the clinical utility of diagnostic tests to exclude alternative diagnoses in people meeting the diagnostic criteria for IBS.</li> <li>I think the discussion of what to do with patients who have redflag symptoms, or who fail to respond to initial treatment should include a mention of re-evaluation for possible malignancy. The gL says</li> <li>What is the role of red flag symptoms alongside diagnostic criteria IBS diagnosis?</li> <li>• The Manning criteria do not consider red flag symptoms. The addition of red flag symptoms</li> <li>6 seems to enhance diagnostic accuracy (Paterson 1999, Canadian IBS position statement).</li> <li>7 The GDG considered this aspect of the review at length, recognising the need for 8 recommendations supporting the IBS algorithm to ensure that red flag symptoms take the</li> </ul>	Thank you for your comments. Re evaluation of red flag symptoms is included in the follow up section.

Туре	Stakeholder	N O	Docu ment	Section number	Comments	Developer's Response. Please respond to all comments
					<ul> <li>9 patient out of this guideline and into other related NICE guidance.</li> <li>10 • The addition of red flags to the Manning criteria increases the PPV of Manning and Rome I</li> <li>11 and II (Vanner 1999; Hammer 2004).</li> <li>12 • Red flag symptoms – these seem to enhance original criteria and importantly relate this</li> <li>13 guidance to other relevant NICE guidelines, in particular NICE Clinical Guideline 27</li> <li>14 'Suspected Cancer Referral' published in 2005.</li> <li>You should ask them to mention that unexplained weight loss may be a symptom of PC or other upper GI cancer (also consider cancer in )the patients who do not meet the diagnostic criteria for IBS, and those with red flag or other persistent symptoms, especially in the over 50 age group."</li> <li>Just because few IBS patients were found to have CRC doesn't mean few would be found to have pancreatic cancer if the symptoms are more closely related – which they are.</li> <li>[XXX] says:</li> <li>"The gold standard (editor: for pancreatic cancer diagnosis) is a CT scan of abdo - not mentioned in the IBS diagnostics</li> <li>The most difficult thing would be to define the criteria for scanning, but the IBS criteria are interesting - if I had altered bowel habit and abdo pain for 6 months, I would not be thinking IBS, I'd be thinking cancer.</li> <li>Surely the cost of all the various investigations listed here could justify a single CT abdo"</li> </ul>	

Туре	Stakeholder	N O	Docu ment	Section number	Comments	Developer's Response. Please respond to all comments
					I am afraid we haven't had time to do a full review of the literature to suggest changes of wording in the guidelines but we hope that the guidelines can be modified to correctly reflect the need to rule out pancreatic and ovarian cancer in patients presenting with IBS-like symptoms – not all pancreatic cancer patients present with jaundice just those with tumours in the head of the pancreas or very late presentation of tumours developing in the body and tail of pancreas. Patients with tumours in the body and tail of the pancreas will present with IBS-like symptoms and we must find a way to differentiate IBS and cancer. We would be happy to contribute to any changes to the IBS guidelines.	
SH	Ovarian Cancer Action (joint comments with Pancreatic cancer UK)	7	Full	General	Pancreatic Cancer has the lowest survival rate of all cancers. A significant reason for this is late diagnosis partly due to lack of recognised early symptoms and partly due to commonality of symptoms with other benign conditions such as IBS. There is conflicting opinion about whether symptoms of pancreatic cancer can be distinguished from IBS or not eg medical advisor of IBS network says no way should they be confused whereas gastroenterologists say there is no way they can be distinguished/differentiated. It is therefore of concern that no mention of this is made in the guidelines for diagnosis of IBS. We have not had time to research the literature to find references to support either argument. This issue must be highlighted in the guidelines if we are ever to make progress with earlier/faster diagnosis of pancreatic cancer. Your authors may be best placed at this time to provide guidance in this area as they have just read the literature but maybe not the literature on symptoms and diagnosis of pancreatic cancer. I do hope some attempt can be made in these guidelines to highlight and	Thank you for your comments Please contact NICE re suspected cancer referral guidelines.

Туре	Stakeholder	N O	Docu ment	Section number	Comments	Developer's Response. Please respond to all comments
					resolve this issue. The IBS symptoms listed seem very similar to those of pancreatic cancer and I can't find any that would clearly show IBS rather than pancreatic cancer. [XXX]	
SH	Oxford Nutrition Ltd				This organisation was approached but did not respond.	
SH	Pancreatic Cancer UK				This organisation was approached but did not respond.	
SH	Peckforton Pharmaceuticals Ltd	1	Full	General	The Guidelines present a comprehensive literature review but offer little in the way of interpretation of the data and the recommendations at the end of each section are so brief and general that they are not particularly useful.	Thank you for your comment
SH	Peckforton Pharmaceuticals Ltd	2	Full	8	The review of pharmacological approaches while detailed seems to ignore some established symptomatic therapies such as deflatulents (i.e. simethicone) and also some more recently approved therapies such as 5HT receptor antagonists. The only neuropeptides discussed are the SSRI's.	Thank you for your comments. This is outside the scope of the guideline
SH	Peckforton Pharmaceuticals Ltd	3	Full	8	Related diseases such as dyspepsia are also ignored. Functional dyspepsia and IBS have both been classified as psychological G.I. disorders. Furthermore population based studies have identified a considerable overlap between functional dyspepsia and IBS. In fact an epidemiological study concluded that "separation of functional gastrointestinal symptoms into dyspepsia, its subgroups and IBS may be inappropriate". It would seem therefore a discussion of dyspepsia related treatments such as antacids may be warranted.	Dyspepsia is covered under separate NICE Guidance
SH	Peckforton Pharmaceuticals Ltd	4	Full	8.3	The Guidelines also seem to be in conflict with recent recommendations by other National Academic Institutions. For example there is little discussion of a multiple symptom relief approach. In fact recommended patient pathways for treatment such as presented in Figure 17 on page 330 suggest treating to a maximum	Thank you for your comment. See Algorithm –single or combination therapies together with lifestyle diet and physical activity are considered depending on the individual symptom profile.

Туре	Stakeholder	N O	Docu ment	Section number	Comments	Developer's Response. Please respond to all comments
					Gastroenterology, Functional Disorder Task Force recommendation that " treatment targeted toward a single IBS symptom is suboptimal"	
SH	Peckforton Pharmaceuticals Ltd	5	Full	General	Pivotal to the discussion at this point is the frequently reported finding that single symptom treatment of IBS often fails to provide satisfactory relief and may be associated with numerous adverse events due to dose escalation.	Thank you for your comments See above
SH	Peckforton Pharmaceuticals Ltd	6	Full	General	It is perhaps a little disappointing therefore that in such a comprehensive guideline there is so little discussion to the multiple symptom relief approach as recently recommended by bodies such as the American College of Gastroenterology.	Thank you for your comments See above
SH	Pelvic Pain Support Network	1	Full	General	Although there is acknowledgment of the Rome 111 criteria this does not seem to have been incorporated fully into the summary. Important factors are the number of days of pain per month and whether the pain is cyclical in women.	Thank you for your comments
SH	Pelvic Pain Support Network	2	Full	General	"Impact of irritable bowel syndrome on health related quality of life" Amouretti M et al Gasteroenterol Clin Biol 2006 Feb This appears to have been omitted from the HRQOL studies. The IBS QOL was used for this in addition to the SF36. The article concludes that IBS has a significant impact on HRQOL of patients. In addition specific characteristics such as gender, symptom severity and time since onset of symptoms are predictive of more impaired health-related quality of life. This study should be included as it uses a disease specific measure of HRQOL in addition to a generic assessment tool.	Thank you for your comment. Amouretti (2006) has been added to the review of HRQoL data.
SH	PERIGON Healthcare Ltd				This organisation was approached but did not respond.	
SH	Primary Care Pharmacists Association				This organisation was approached but did not respond.	
SH	PRIMIS+				This organisation was approached but did not respond.	
SH	Procter and Gamble				This organisation was approached but did not respond.	

Туре	Stakeholder	N O	Docu ment	Section number	Comments	Developer's Response. Please respond to all comments
	Pharmaceuticals					
SH	Prodigy				This organisation was approached but did not respond.	
SH	Reckitt Benckiser Healthcare (UK) Ltd				This organisation was approached but did not respond.	
SH	Royal College of General Practitioners				This organisation was approached but did not respond.	
SH	Royal College of Midwives				This organisation was approached but did not respond.	
SH	Royal College of Nursing	1	NICE	General	The RCN welcomes the guideline and its positive message in primary care.	Thank you for your comments
SH	Royal College of Nursing	2	NICE	General	Differential diagnosis: only bowel cancer or coeliac disease seems to be considered. What about other diagnoses (particularly gynaecological: pelvic congestion, ovarian cancer, gallstones, inflammatory bowel disease, especially Crohn's)?	Thank you for your comments amended
SH	Royal College of Nursing	3	NICE	General	A very common problem is that many IBS patients do not accept their diagnosis and return repeatedly until referred for secondary care/tests. Tendency to refer by assertiveness of patient rather than clinical need/symptoms. Which IBS patients should eventually be referred (or as implied at present, is it intended that none get to secondary care)?	The GDG will be working with the NICE implementation team to highlight this issue with healthcare professionals. The
SH	Royal College of Nursing	4	NICE	Introducti on	Introduction: does IBS include Rome 11 idiopathic constipation and diarrhoea?	Thank you for your comments. Idiopathic constipation and diarrhoea separate parts of Rome II
SH	Royal College of Nursing	5	NICE	introducti on	Older person: less likely to have IBS, more likely to have diverticular disease or malignancy? Do you need different alarm signals by age?	
SH	Royal College of Nursing	6	NICE	1.1	Contradiction in asking directly and asking only open questions?	Thank you for your comment amended

Туре	Stakeholder	N O	Docu ment	Section number	Comments	Developer's Response. Please respond to all comments
SH	Royal College of Nursing	7	NICE	1.1.1.1	How often & how severely should symptoms occur within the 6 months?	Thank you for your question. The frequency and severity will be determined by the individual person, detailed by patient history.
SH	Royal College of Nursing	8	NICE	1.1.1.2	Criteria very gut focused and not specific. How much weight loss over what period? How much/often bleeding (most constipated patients will have some)? How close family history? Menstrual disturbances? "Any" of above implies of any severity. Tests not done: is this age related? How does this fit with publicity for bowel screening encouraging even asymptomatic people to have tests? Ova and parasites indicated with exotic travel?	Thank you for your comment. Severity is subjective and therefore described by individual patient and assessed by the clinician. Tests not done to confirm diagnosis of IBS is differential diagnosis suspected e.g. parasitic infection following exotic travel then appropriate investigations are indicated.
SH	Royal College of Nursing	9	NICE	1.1.1.3	Altered bowel habit/stool form: again need to define better? Necessary to specify likely bladder symptoms, or any balder symptoms at all?	Thank you for your comment Altered bowel habit is subjective and person specific so will be defined by the person with symptoms as part of patient history. Bladder symptoms are included in non colonic symptoms.
SH	Royal College of Nursing	10	NICE	1.2.1.1	How much physical activity is recommended? Is this whatever the baseline is (some of these young women exercise excessively already?)	Thank you for your comment The amount of physical activity is recommended by the Chief Medical Officer report for the maintenance of general health.
SH	Royal College of Nursing		NICE	1.2.1.4	Tea and coffee or all caffeinated drinks? What about the DoH 5 fruit & vegetables a day?	Thank you for your comment. Tea and coffee are most commonly consumed caffeinated drinks.
SH	Royal College of Nursing	12	NICE	1.2.1.5	How is it suggested to review fibre intake?	Thank you for your question.

Туре	Stakeholder	N O	Docu ment	Section number	Comments	Developer's Response. Please respond to all comments
						Fibre intake would generally be reviewed by primary healthcare professional, specific or complex cases would be referred to a dietitian.
SH	Royal College of Nursing	13	NICE	1.2.1.5	Put foods before medications in fibre supplements.	Thank you for your comment.
SH	Royal College of Nursing	14	NICE	1.2.2.4	Too specific in stool form: keep more general: easy to pass without urgency or leakage? Type 4 may cause incontinence in those with weak muscles?	Thank you for your comment. The Bristol Stool chart is a validated tool and is used as a general guide.
SH	Royal College of Nursing	15	NICE	1.2.2.5	How long to try antidepressants for before up dose/change? If follow up at 4 weeks implied change then?	Thank you for your question. Follow up at 4 weeks monitors effect, dose would be altered depending on the response of the person taking the medication.
SH	Royal College of Nursing	16	NICE	Research question 4.2	Equally as effective as what, or each other?	Thank you for your comment. This research is a head to head comparison of psychological therapies, so they are being compared against each other.
SH	Royal College of Nursing	17	NICE	General	Was there any evidence on the role of the IBS nurse specialist?	Thank you for your comment. This was outside the scope of the guideline.
SH	Royal College of Paediatrics and Child Health				This organisation was approached but did not respond.	
SH	Royal College of Pathologists				This organisation was approached but did not respond.	
SH	Royal College of Physicians of Edinburgh				This organisation was approached but did not respond.	
SH	Royal College of Physicians of London	1	Full	1.1.1	Putting the change in bowel habit first is unfortunate since the thing that makes one most happy about diagnosing IBS is a long history of more than 2 years in Kruis experience <sup>1</sup> . I prefer that you put abdominal pain and discomfort first and put "associated with disturbed bowel habit" second. Change in bowel habit especially	Thank you for your comment. This has been amended

Туре	Stakeholder	N O	Docu ment	Section number	Comments	Developer's Response. Please respond to all comments
					in an elderly patient makes one think of colorectal cancer. This is why most definitions insist on chronicity ie > 6months to ensure it is not the prodrome of a more serious illness or some transient disturbance	
SH	Royal College of Physicians of London	2	Full	1.1.1.2	Red Flags – While I have no problem with weight loss, rectal bleeding and apparent history of colorectal cancer I would like to see this match with the red flags in the BSG guidelines so I would also add: " nocturnal symptoms, recent antibiotic use and age greater than 50 together with a short history ". All of these factors significantly alter the probabilities of IBS <sup>2</sup> , <sup>3</sup> (See BSG Guidelines <sup>4</sup> ) and one page summary for GPs at the end of this document	Thank you for your comment. The GDG discussed this and decided not to amend the diagnostic criteria.
SH	Royal College of Physicians of London	3	Full	1.1.1.3	Here you have adapted existing criteria without acknowledging this. This is a combination of the Rome III definitions and Rome II and Manning. The audience who may be familiar with any of these may be confused. The trouble is that many of these symptoms are non specific like symptoms made worse by eating (biliary pain, pancreatic pain, peptic ulcer pain and functional dyspepsia for example). While other features such as passage of mucous correlate poorly with any other symptoms. It is for this reason that Rome III did not include this criteria but simply stated that the diagnosis was "supported if these features were present" which is what I think you should state. I would exclude that symptoms were made worse by eating or mention that this is non-specific and does not help the differential diagnosis.	Thank you for your comment The full version has been amended regarding the adaptation of existing criteria. The GDG discussed supportive features of IBS at length, and disagreed with this feedback. In particular with comments made about the presence of mucous as a diagnostic aid.
SH	Royal College of Physicians of London	4	Full	1.1.2.2	I am unhappy with the present recommendation not to do flexible sigmoidoscopy since 20% of patients over the age of 70 with severe diarrhoea will in fact have microscopic colitis and only be diagnosable by a flexible sigmoidoscopy and biopsy <sup>5</sup> . Since there are specific treatments to this condition it will be important to add	Thank you for your comment. People who do not meet the IBS criteria or who have red flags should be referred for further investigation including sigmoidoscopy if appropriate.

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					this as a caveat. Either add an age limit on the alarm symptoms, ie patients >50 should be considered to have alarm symptoms and be more thoroughly investigated or specify that flexible sigmoidoscopy may be beneficial in elderly patients with marked diarrhoea. You could also get round this problem by including the nocturnal diarrhoea as an indication or investigations since people with microscopic colitis usually suffer from this.	
SH	Royal College of Physicians of London	5	Full	1.2.1.1	While self help is entirely laudable, there is a discrepancy with the level of evidence which is rather weak for exercise. The quoted study by Cauldwell could all be placebo since it was uncontrolled. The epidemiological experience is unhelpful as it does not usually provide any mechanism and could all be due to confounding with other variables. In truth exercise is almost certainly good for you but there is no evidence that it really effects GI function except in extremes. I would make the advice more cautious and acknowledge the lack of strong evidence	Thank you for your comments. All the reviews in the diet, physical activity, lifestyle and self help sections acknowledge the paucity of current evidence. The recommendations are in line with the current DoH reports for maintaining and improving general health.
SH	Royal College of Physicians of London	6	Full	1.2.1.5	While part of this recommendation is rigorously evidence based the advice to take oats has no evidence base. Food is a very complicated substance and whole foods have many other components other than fibre. I think it is for this reason that the best evidence is for ispagula. My personal experience is the patients who are intolerant of bran and whole wheat are often also intolerant of whole oats but as I mentioned there really is little evidence about this.	Thank you for your comments. Ispagula and Oats were used as examples of soluble fibre.
SH	Royal College of Physicians of London	7	Full	1.2.2.4	While you have carefully evaluated studies on behavioural therapy which use only 10 subjects you have ignored the studies on 5HT3 antagonists which included tens of thousands of patients. I think this is a claring omission which must be acknowledged and some how dealt with. The trials are models of how to	The new 5HT3 antagonists were excluded from this guideline as they are not licensed in the UK.

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					conduct studies in IBS and need commenting on even if you have to conclude that at present the drugs are not available. Although Alosetron is not available in the UK Ondansetron is and at least according to one small clinical trial can have a beneficial effect <sup>6</sup> .[XXX]. I would like to suggest that you should recommend that this be evaluated in a large RCT	
SH	Royal College of Physicians of London	8	Full	1.2.2.5	Although you recommend trycyclics at low dose there is in truth only clinical experience to justify this. There is no randomised control trial and given the very strong placebo element in IBS this is essential to do before we can make a strong recommendation. By contrast, there are four randomised control trials of SSRI's at conventional doses which show benefit. It would prefer that you quoted these and added amitriptyline as a clinical recommendation with a low level of evidence	Recommendations should not be graded or contain evidence statements. The evidence statements and GRADE tables already indicate that the evidence is weak for TCAs
SH	Royal College of Physicians of London	9	Full	1.2.3	The recommendation to use psychological treatments rather glosses over the reports that a substantial number (40-50%) of patients allocated to either CBT or psychological treatments drop out and fail to complete which suggests that patients are reluctant to spend so much time on treatment This is of course the attraction of pills! Similar considerations apply to exclusion diets I think that at present you are in danger of making recommendations which will seem unrealistically demanding. The truth is that alosetron was extremely popular with patients because unlike behavioural therapy or dietary exclusions it was easy to take.	Thank you for your comments
SH	Royal College of Physicians of London	10	Full	General	General Comments Overall I think this is a superb effort and has an enormous potential for good. You need somewhere to emphasise that managing IBS correctly will make a big difference to the management of other diseases since there sheer numbers mean that mismanagement and	Thank you for your comments

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					over investigation can have profound influences on waiting lists and availability of resources for other patients with inflammatory bowel disease or colorectal cancer who really need to tests. Getting IBS right is of vital importance for managing all GI patients.	
SH	Royal College of Psychiatrists				This organisation was approached but did not respond.	
SH	Royal College of Radiologists				This organisation was approached but did not respond.	
SH	Royal Liverpool Children's Hospital				This organisation was approached but did not respond.	
SH	Salford PCT				This organisation was approached but did not respond.	
SH	Sandwell PCT				This organisation was approached but did not respond.	
SH	Scottish Intercollegiate Guidelines Network (SIGN)				This organisation was approached but did not respond.	
SH	Scottish Nutrition & Diet Resources Initiative				This organisation was approached but did not respond.	
SH	Sedgefield PCT	1	NICE	1.1	The recommendations on diagnosis and initial assessment are well- constructed, clear and concise. To help clinicians we recommend that particular attention is paid to these in the QRG	Thank you for your comments
SH	Sedgefield PCT	2	NICE	1.2.1.2/1. 2.1.3	We don't question whether these statements are useful, but in the 'Real World' of 10 minute GP consultations we have to prioritise. If using these particular interventions are cost-effective of our time then we suggest you retain "should"; otherwise we suggest that the paragraphs are broader in their recommendations	Thank you for your comments
SH	Sedgefield PCT	3	Full	7.3 (Full); NICE 1.2.14/ 1.2.1.5	Your metanalyses are very clear and helpful. The idea that soluble fibre is preferable is a point well-made. However, some of the evidence fails to attain statistical significance- thus the recommendation that patients should "avoid insoluble fibre" (especially in constipation- predominant IBS who may reasonably benefit) appears barely supported. I suspect this response is fulfils NICE's requirement to avoid 'grey' recommendations, but it doesn't appear justified on the evidence. Additionally most oat fibre is contaminated with wheat	There was insufficient evidence from trials of insoluble fibre to show if there was deterioration in global symptoms, but there was sufficient evidence to show no global improvement. The GDG considered other types of of studies (survey) and drew on their experience to make the recommendation.

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					during production and, therefore the results may be not be all they seem	
SH	Sedgefield PCT	4	NICE	1.2.2.3	As antispasmodics tend to be used predominantly in diarrhoea-predominant IBS, this statement may confuse. Is it intended that Loperamide is used before anti-spasmodics or for management of stool frequency in isolation? In practice, the use of antispasmodics as 1 <sup>st</sup> line Rxs is preferable as their success helps confirm the diagnosis – this is undoubtedly more important in Primary Care where symptoms are less florid, and uncertainty greater	Thank you for your comment. The drug management strategy should be based on the nature and severity of the symptoms and individual or combinations of medication directed at the predominant symptom/s'
SH	Sefton PCT				This organisation was approached but did not respond.	
SH	Sheffield Children's Hospital Trust				This organisation was approached but did not respond.	
SH	Sheffield PCT				This organisation was approached but did not respond.	
SH	Sheffield Teaching Hospitals NHS Foundation Trust	1	NICE	1.2.1.5	The document refers to primary care clinicians to look at and alter a persons fibre content (usually decreasing) but there is no mention of this treatment being tailored to the individual and the timescale involved in this alteration of diet as it may not need to be longer term and is very much dependent on the individual and their existing diet.	Thank you for your comments The diet and lifestyle management strategy should be based on the nature and severity of the symptoms and individual or combinations of dietary manipulation and medication directed at the predominant symptom/s'. IBS is a lifelong condition the management is ongoing.
SH	Sheffield Teaching Hospitals NHS Foundation Trust	2	NICE	Key priorities	There is no obvious mention of a referral to a dietitian to facilitate this individual tailoring of the diet within the text.	Thank you for your comment. A dietitian is a health professional. See 1.2.1.8 The full guideline gives more detail of dietetic input.
SH	Sheffield Teaching Hospitals NHS Foundation Trust	3	NICE	1.2.1.4	There is specific dietary advice but once again it is questionable if primary care clinicians should be giving this level of advice. It may be more appropriate to provide general healthy eating advice along with activity	Thank you for your comment. A dietitian is a health professional and is included in the primary healthcare team.

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					and if there is no improvement to refer to a dietitian for more specific dietary advice. Linked to this dietitians are featured higher up in the algorithm in appendix C but this doesn't match within the body of the guideline.	See 1.2.1.8 The full guideline gives more detail of specialised dietetic input.
SH	Solvay Healthcare Limited				This organisation was approached but did not respond.	•
SH	Staffordshire Moorlands PCT				This organisation was approached but did not respond.	
SH	Stockport PCT				This organisation was approached but did not respond.	
SH	Sussex Cancer Network	1	Full	general	There are serious concerns from the Sussex Cancer Network colorectal tumour group about adopting the NICE proposed guidelines for IBS. They fail to deal with the real risk of excluding Colorectal cancer or inflammatory bowel disease. One of the recommended positive diagnostic symptoms for IBS is a change of bowel habit. A change of bowel habit of greater than 6 weeks is one of the NICE Two week referral criteria for Colorectal Cancer! There is therefore much room for confusion for GPs around which pathway a patient should go down. Most experienced clinicians would be asking for much more Colonoscopy input and making it mandatory in any new patient presenting after 50 before a diagnosis of IBS is made. There are grave concerns from the network colorectal tumour group that, if these guidelines are adopted, diagnoses of colorectal cancer could be delayed or missed. There should therefore be a reconsideration of the diagnostic symptoms for IBS in collaboration with colleagues specialising in colorectal cancer to avoid any potential confusion.	Thank you for your comments Any person with symptoms that meet the NICE suspected Cancer referral guidance should be referred. The criteria for excluding colorectal cancer and IBD are specific and patients with other red flags should be referred for further investigations. The evidence from the diagnostic criteria review shows that use of the criteria together with red flag symptoms does differentiate between suspected colorectal cancers and IBS.
SH	Syner-Med				This organisation was approached but did not respond.	

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SH	The David Lewis Centre				This organisation was approached but did not respond.	
SH	The IBS Network (Now The Gut Trust)	1	NICE	General	Experience with EPP shows it helps people with illness if they are referred to as people with, not patients or sufferers	Thank you for your comments amended
SH	The IBS Network (Now The Gut Trust)	2	NICE	1.1.2.2	Whilst we welcome the positive diagnosis approach, it is important to recognise the peace of mind and reassurance that such tests, when negative, can provide the patient.	Thank you for your comments
SH	The IBS Network (Now The Gut Trust)	3	NICE	1.1.2.2	This section seems over-rigid and does not seem to permit medical practitioners enough latitude to perform invasive tests should they think them necessary or that the circumstances require them	Thank you for your comments. This recommendation is based on the evidence that these tests are not required to make a positive diagnosis of IBS based on the criteria and absence of red flags. NICE guidance does not replace clinical judgement.
SH	The IBS Network (Now The Gut Trust)	4	NICE	1.2.1.1	We welcome the stress on self-help. However, it is essential that this is sufficiently resourced, and that those organisations which provide self-help information and support are supported in doing so.	Thank you for your comments Resource provision is beyond the scope of this guideline
SH	The IBS Network (Now The Gut Trust)	5	NICE	1.2.1.1	GP consultations do not provide enough time for sufficient information to be supplied about an illness like IBS. It is essential that a referral to suitable self help organisations is made by the GP, at the consultation.	Thank you for your comments They have been referred to the implementation team.
SH	The IBS Network (Now The Gut Trust)	6	NICE	1.2.1.5	We fully support the long overdue advice on fibre consumption	Thank you for your comments
SH	The IBS Network (Now The Gut Trust)		NICE	1.2.1.2	This advice needs to be strengthened with examples, and care needs to be taken that it is not seen by the patient as a brush-off with some self-evident advice. Relaxation courses provided through the GP's surgery would assist here.	Thank you for your comments
SH	The IBS Network (Now The Gut Trust)	8	NICE	1.2.1.6	We are concerned at the non-specific nature of this advice. Probiotic products may be effective when in the correct strength, using the correct constituents, and with the correct delivery methods. We are concerned that	Thank you for your comments

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					this advice could be misused in marketing and promotional materials by products whose efficacy has not been proven.	
SH	The IBS Network (Now The Gut Trust)	9	NICE	1.2.1.8	Dieticians to whom referrals are made should have some specialism in IBS. 'Good' dietary advice for people with IBS frequently differs markedly from those for people with different conditions and generalist advice will not be of use.	Thank you for your comments
SH	The IBS Network (Now The Gut Trust)	10	NICE	1.2.2.5	It is essential that the medical practitioner explains to the person with IBS why tricyclics or SSRIs are being prescribed so that there is no suggestion of it being a treatment for mental illness or depression.	Thank you for your comments Tricyclics or SSRI's are being recommended for patients with IBS who have not responded to conventional treatment. They are being recommended because the evidence suggests that in moderate to low doses they can be helpful in reducing certain symptoms of IBS (mainly pain).
SH	The IBS Network (Now The Gut Trust)	11	NICE	1.2.2.6	Experience suggests that SSRIs exacerbate IBS-D.	Thank you for your comments
SH	The IBS Network (Now The Gut Trust)		NICE	1.2.4	We believe that complementary therapies can help those who have confidence in the therapist and that a blanket ban fails to take into account the variation between therapist quality or patient commitment to, and belief in, the therapy.	Thank you for your comments. Currently NICE requires that the recommendations based on clinical trial evidence for CAM.
SH	The IBS Network (Now The Gut Trust)	13	NICE	1.2.4	We regret that the guidelines process did not study complementary therapies in depth since whilst there may be little clinical evidence for them, it is our experience that many can provide some symptom relief, and a degree of comfort and reassurance.	Thank you for your comments. Currently NICE requires that the recommendations based on clinical trial evidence for CAM.
SH	The IBS Network (Now The Gut Trust)	14	NICE	1.2.4.1	Some people find both acupuncture and reflexology useful. It should be mentioned with the caveat that there is no clinical data to support its use.	Thank you for your comments. Currently NICE requires that the recommendations based on

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						clinical trial evidence for CAM.
SH	The ME Association				This organisation was approached but did not respond.	
SH	The National Pharmaceutical Association				This organisation was approached but did not respond.	
SH	The Neurological Alliance				This organisation was approached but did not respond.	
SH	The Pernicious Anaemia Society				This organisation was approached but did not respond.	
SH	The Prince's Foundation for Integrated Health				This organisation was approached but did not respond.	
SH	The Royal College of Surgeons Edinburgh				This organisation was approached but did not respond.	
SH	The Royal Society of Medicine				This organisation was approached but did not respond.	
SH	The Society and College of Radiographers				This organisation was approached but did not respond.	
SH	The Survivors Trust				This organisation was approached but did not respond.	
SH	UK Clinical Pharmacy Association				This organisation was approached but did not respond.	
SH	UK Coalition of People Living with HIV & AIDS				This organisation was approached but did not respond.	
SH	University College London Hospitals NHS Foundation Trust				This organisation was approached but did not respond.	
SH	University Hospital Birmingham NHS Foundation Trust				This organisation was approached but did not respond.	
SH	University of Birmingham, Department of Primary Care & General Practice				This organisation was approached but did not respond.	
SH	Welsh Assembly Government				This organisation was approached but did not respond.	
SH	Welsh Scientific Advisory Committee (WSAC)				This organisation was approached but did not respond.	
SH	Western Cheshire Primary Care Trust				This organisation was approached but did not respond.	
SH	Whipps Cross University Hospital NHS Trust				This organisation was approached but did not respond.	

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SH	Wyreside Products Ltd	1	Full	7	There appears to be no guidance on measures to ensure that where there are restricted diets how a patient can be helped from having deficiencies in essential nutrients (i.e. those that feature in the PARNUTS list). As a short-term measure this could include the use of supplements that provide substances covered by PARNUTS. Where there has been a large degree of self-diagnosis and diet exclusion, this measure may help the patient's general health prior to closer examination by a Dietitian or qualified nutritionist.	Thank you for your comments the guideline can only make recommendations based on clinical evidence.
SH	Wyreside Products Ltd	2	NICE	1.2.1.4	There appears to be no guidance on measures to ensure that where there are restricted diets how a patient can be helped from having deficiencies in essential nutrients (i.e. those that feature in the PARNUTS list). As a short-term measure this could include the use of supplements that provide substances covered by PARNUTS. Where there has been a large degree of self-diagnosis and diet exclusion, this measure may help the patient's general health prior to closer examination by a dietitian or qualified nutritionist.	See above
SH	Wyreside Products Ltd	3	Full	12	There should be research into causes of IBS, and how this relates to effective treatment strategies.	Thank you for your comments
SH	Wyreside Products Ltd	4	NICE	4	There should be research into causes of IBS, and how this relates to effective treatment strategies.	Thank you for your comments. The guidance is limited to six research recommendations.
SH	Wyreside Products Ltd	5	NICE	1.2.1.7	This should be qualified to state that this advice relates particularly to Aloe Vera products that contain the sap and total leaf extracts, since the gel is free of the anthraquinone that are known to have a laxative effect.	Thank you for your comments the guideline can only make recommendations based on clinical evidence. There was no evidence of effectiveness in the products investigated in the review.
SH	Wyreside Products Ltd	6	Full	7	Where are patient presents a legal OTC dietary product they have been trying, if the patient believes that it is helping their condition, the Health professional should	Thank you for your comments the guideline can only make recommendations based on

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					not discourage them from continuing trying the product for at least 4 weeks, as in the case of probiotics, so that the effects can be more fully monitored. These types of products could include substances from the PARNUTS list or permitted novel foods and functional foods with efficacy studies.	clinical evidence.
SH	Wyreside Products Ltd	8	Full	general	Commercial enterprises should be encouraged to take part in the NICE consultations, and also encouraged and assisted in their research programmes that are running to help the cause of the IBS sufferer. It is noted that there are only a few commercial companies that have become stakeholders in this consultation. How can this be address?	Thank you for your comments. NICE stakeholder inclusion is open to all organisations – registration is via the NICE website and all stakeholders are encouraged to submit/contribute to the submission of evidence.
SH	York NHS Trust				This organisation was approached but did not respond.	