NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Centre for Clinical Practice

Review of Clinical Guideline (CG61) – Irritable bowel syndrome in adults: Diagnosis and management in primary care

Background information

Guideline issue date: 2008

3 year review: 2011

National Collaborating Centre: Nursing and Supportive Care

Review recommendation

- The guideline should not be updated at this time
- This guideline may be reviewed again when NICE Diagnostics Assessment Programme publishes the evaluation of SeHCAT.

Factors influencing the decision

Literature search

1. From initial intelligence gathering and a high-level randomised control trial (RCT) search clinical areas were identified to inform the development of clinical questions for focused searches. Through this stage of the process 33 studies were identified relevant to the guideline scope. The identified studies were related to the following clinical areas within the guideline:
    - Pharmacological treatments
    - Psychological therapies
    - Diet and Lifestyle

2. Five clinical questions were developed for more focused literature searches based on the areas above, qualitative feedback from other NICE departments and the views expressed by the Guideline Development Group. In total, 43 studies were identified through the focused searches. There is a small amount of new evidence in all of the areas examined but this is unlikely to be sufficient to change current guideline recommendations

3. A small amount of new evidence was identified which directly answered the research recommendations presented in the original guideline:
    - Psychological therapies
    - Tricyclic Antidepressants

    However, the evidence is unlikely to be sufficient to enable a recommendation to be made.

4. Eleven ongoing clinical trials (publication dates unknown) were identified focusing on:
    - Diagnostic strategies
    - Pharmacological therapies
    - Alternative and complementary therapies
    - Diet and lifestyle modification

Guideline Development Group and National Collaborating Centre perspective

5. A questionnaire was distributed to GDG members and the National Collaborating Centre to consult them on the need for an update of the guideline. Two responses were received with respondents highlighting that since publication of the guideline more literature has become available on the effect of dietary management of short chain fermentable carbohydrates (FODMAPs) on IBS related symptoms. This feedback contributed towards the development of the clinical questions for the focused searches.

6. No ongoing research was cited by GDG members.

7. Neither of the respondents commented on whether they felt there is variation in current practice supported by adequate evidence at this time to warrant an update of the current guideline.

Implementation and post publication feedback

8. In total 49 enquiries were received from post-publication feedback, most of which were routine, or enquiries that related to the interpretation of the document. No key themes emerging from post-publication feedback contributed towards the development of the clinical questions as described above.

9. An analysis by the NICE implementation team indicated that presentation of the guidance needs to be clearer for GPs, and the role of dieticians was important and raised the question of how they will be funded.

Relationship to other NICE guidance

10. NICE guidance related to CG61 can be viewed in Appendix 1.

Summary of Stakeholder Feedback

Review proposal put to consultees:
The guideline should not be updated at this time.
The guideline will be reviewed again according to current processes.

11. In total 18 stakeholders commented on the review proposal recommendation during the 2 week consultation period.

12. The majority of stakeholders agreed with the decision not to update the guideline at this stage. Stakeholder comments can be viewed in Appendix 2

13. The stakeholders who disagreed felt that the following areas should be considered for review in an update of the guideline, and submitted literature to support their decision:
    - Diagnosis: Stakeholders felt that differential diagnoses for IBS could be improved. In particular stakeholders mentioned screening for Irritable Bowel Disease using faecal calprotectin test, and for bile acid malabsorption using SeHCAT (Tauroselcholic [^{75} Selenium] acid). The current guideline does recommend that patients presenting with IBS symptoms should be assessed for inflammatory markers for inflammatory bowel disease, and so this does not contradict current recommendations. However, the NICE Diagnostics Assessment Programme is currently evaluating SeHCAT which may improve differential diagnosis in due course.
    - Probiotics: One stakeholder felt that further investigation of the evidence relating to probiotics would identify which probiotic works best for which type of patient. To address this, the results of the RCTs identified in this review would need to be synthesized in a meta-analysis. However, there is a large amount of heterogeneity between the studies due to a large number of different probiotic formulations currently on the market, and so meta-analysis is not possible at this time.

14. During consultation one stakeholder commented that ultrasound was not covered in the guideline, although they agreed that the guideline should not be updated at this time.

Anti-discrimination and equalities considerations

15. No evidence was identified to indicate that the guideline scope does not comply with anti-discrimination and equalities legislation. The original scope is inclusive of adults (aged 18 and over) who present at primary care with symptoms suggestive of IBS.

Conclusion

16. Through the process no additional areas were identified which would indicate a significant change in clinical practice. There are no factors described above which would invalidate or change the direction of current guideline recommendations.

17. The guideline should not be considered for an update at this time. This decision may be reviewed again when NICE Diagnostics Assessment Programme publishes the evaluation of SeHCAT in 2012.

Relationship to quality standards

18. This topic is not currently being considered for a quality standard

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Centre for Clinical Practice
12/07/11

Appendix 1

The following NICE guidance is related to CG61:

Guidance	**Review date**
CG90 (replaces CG23) Depression in adults. Issued Oct 2009	October 2012
CG91 Depression with a chronic physical health problem. Issued Oct 2009	October 2012
Related NICE guidance not included in CG61	
CG86 Recognition and assessment of coeliac disease Issued: May 09	May 2012
CG49 Faecal incontinence: the management of faecal incontinence in adults Issued: Jun 2007. 1st Review Dec 2010	June 2013
Related NICE guidance in progress	
Chron's Disease	Wave 22, Due: December 2012
Ulcerative Colitis	Wave 25, Due: TBC

Appendix 2

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	
Sheffield Teaching Hospitals NHS Foundation Trust	Agree	I agree that the GL should not be updated yet			Thank you.
The British Psychological Society		If you have not received a reply from us by the consultation close date, please assume that the Society does not disagree with your recommendation *not* to undertake an update at this time.			Thank you.
Pancreatic Cancer Scotland		A diagnosis of IBS should be considered only if the person has abdominal pain or discomfort that is either relieved by defaecation or associated with altered bowel frequency or stool form. This should be accompanied by at least two of the following four symptoms: altered stool passage (straining, urgency, incomplete evacuation) abdominal bloating (more common in women than men), distension, tension or hardness symptoms made worse by eating passage of mucus. Other features such as			Thank you. NICE make recommendations based on evidence that is reviewed by a Guideline Development Group (GDG). Whilst your suggestions are useful they cannot be proposed for inclusion in the guideline without a review of the necessary evidence bases and GDG consensus. No new evidence was identified in the areas you mention during the review process which would

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	
		lethargy, nausea, backache and bladder symptoms are common in people with IBS, and may be used to support the diagnosis.			warrant an update of the guideline at this stage. Your comments will be considered at the next review.
The British Society of Paediatric Gastroenterology, Hepatology and Nutrition (BSPGHAN)	Disagree	The document, as it stands, treats probiotics as a unitary therapy, so that failure to respond to one preparation thereby is taken to undermine the validity of the approach in general. This does not concord with current recognition that different organisms may have different effects (Murch S. Probiotics as mainstream allergy therapy? Arch Dis Child 2005; 90: 881-882). I believe that the statement that "Further investigation of this area is unlikely to result in evidence to inform new recommendations or change existing ones" is not justified, in that a number of RCT's did show benefit. Surely further investigation of the area is warranted, aiming to identify which probiotic or probiotic compound may benefit which type of patient.			Thank you. The RCTs that we have identified examine a wide range of probiotic organisms which have different mechanisms of action. This amount of variety prevents the results being synthesised in a meta analysis, and so further investigation at this time would not enable us to identify which probiotic benefit which patients. However, as research in this area grows it may become possible to do this in the future, and will be monitored in subsequent updates of this guideline.
The Irritable Bowel Syndrome	Disagree	Agree on most of the issues considered but	Consider the following points		

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Network					
The Irritable Bowel Syndrome Network			Include faecal calprotectin as screening test for IBD		Thank you. Recommendations already exist in the current IBS guideline in relation to screening for inflammatory markers for IBD. Faecal calprotectin is one such marker and is therefore already included.
The Irritable Bowel Syndrome Network			Include CA125 as screen for ovarian cancer and pelvic ultrasound for women with pelvic pain over 50.		Thank you. Recommendations already exist in relation to CA125 screening in women suspected with ovarian cancer in primary care. This is covered in the NICE guideline CG122 Ovarian Cancer and will be cross referred to as appropriate.
The Irritable Bowel Syndrome Network			Include FOB as screen for ca bowel esp for older patients		Thank you. The current guideline already cross refers to the NICE guideline CG27 Referral Guidelines for Suspected Cancer where specific recommendations are made for screening for cancer.
The Irritable			Dietary advice: 8		The purpose of this review is

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Bowel Syndrome Network			cups of fluid a day, ?evidence		to identify areas where new research is available. No new evidence relating to drinking fluid was identified which would enable guideline recommendations to be made or changed.
The Irritable Bowel Syndrome Network		Comment on FODMAPS relevant here	Review recent evidence on fibre (which patients, useful for constipation) and oats (for bloating) and on fruit (which fruits).		Thank you. Evidence relating to FODMAPS was identified during this review and the evidence base found was small. Further high quality research is needed if recommendations relating to FODMAPS are to be made in subsequent reviews of this guideline.
The Irritable Bowel Syndrome Network		• What is distinction between psychological therapy and CBT? Other modalities of psychotherapy, (re: Guthrie et al). I think it would be relevant to include comment on relaxation therapy • Did committee question continued utility of Rome Criteria? Diagnosis by committee. Has it provided insights re causation, improvement re management?			Thank you. No evidence was found in the areas that you highlight that would warrant review of the guideline at this stage. Your comments will be considered in the next scheduled review.

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		• Review recent evidence for exclusion diets. Do they trap people in IBS? • Would committee support proposal that IBS should be predominantly managed in primary care by non medical hcps (practice nurses, dietitians or counsellors) and supported by the self care resources of the charities sector (The IBS Network). • Cholestyramine is a very useful first line treatment for diarrhoea assoc with urgency and incontinence. Cf. Proposed guidelines on bile acid malabsorption. • Only discourage the use of complementary therapies if there is risk to patient. Indications are that the holistic, patient centred approach offered can be helpful. Would committee offer generic support to complementary therapies?			
NHS Direct	Agree				Thank you.
Medicines and **H**ealthcare products **R**egulatory **A**gency	Agree	We are not aware of any reason why NICE should update the guidance on diagnosis and management of irritable bowel syndrome at this point.			Thank you.
British Nuclear	disagree	There is growing evidence that many patients (up	In view of		Thank you. SeHCAT is

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	
Medicine Society (BNMS)		to 30%) with IBS may actually be suffering from bile acid malabsorption. In the UK we SeHCAT is more and more used for patients with IBS and as one speaker recently mentioned (big advocates are Professor of Thandu Bardhan (Rotherham), Dr. Dr Jervoise Andreyev (Royal Marsden) and , this test should be performed by the primary care practitioners, before patients are commenced unnecessarily on anti IBS therapy. This test is not available in most of the UK or USA so the literature search outside UK will not show this test at all. If this is implemented in the NICE guidelines it has a profound effect on the practice in the UK. 1. Systematic review: the prevalence of idiopathic bile acid malabsorption as diagnosed by SeHCAT scanning in patients with diarrhoea-predominant irritable bowel syndrome by: L Wedlake, R A'Hern, D Russell, K Thomas, JRF Walters, HJN Andreyev, Alimentary Pharmacology and Therapeutics, Volume 30, Issue 7 pages:707-717, 2009 2. Bile acid malabsorption in persistent diarrhoea. MJ Smith, P Cherion, GS Raju, BF Dawson, S Mahon, KD Bhardan, Journal	prevalence of bile acid malabsorption in this group of patients we recommend SeHCAT assessment in patients with diarrhoea predominant IBS.		currently being appraised for potential review by the Medical Technology Evaluation Programme.

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	
		of the Royal College of Physicians of London, Volume 34, No.5, pages448-451, 2000 3. Systematic Evaluation of Causes of Chronic Watery Diarrhoea with Functional Characteristics, F Fernandez-Banares, M Esteve, A Salas, M Alsina, C Farre, et al. The American Journal of Gastroenterology, Volume 102, Issue 11, pages:2520-2528, 2007			
Royal College of General Practitioners	Agree				Thank you.
The United Kingdom Clinical Pharmacy Association (UKCPA) Gastro/Hep Group	Agree	As there appears to be a lack of conclusive evidence to change recommendations the UKCAP agree that an update is not required.			Thank you.
Previous GDG member	Agree	No Comment			Thank you.
Crohn's and Colitis UK		Our comments relate to an area not covered in the consultation review.			

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	
		Diagnosis We believe that the guidance should be reviewed to improve the potential for differential diagnosis of IBD and IBS. The algorithm for referral for investigation should include: Refer on the basis of a combination of the following: (1) a Family History of IBD (2) raised inflammatory markers (3) positive faecal calprotectin test A meta-analysis published in the BMJ 2010 concluded the test was a valuable diagnostic test for IBD the evidence was not conclusive for use in primary care. http://www.medscape.com/viewarticle/725672 (accessed 16th June 2011) A strong argument for improving differential diagnosis comes from unpublished data obtained from the GPRD through a Crohns and Colitis UK-funded research project at the University of Nottingham. This shows that 10% of patients subsequently diagnosed with IBD were originally diagnosed as IBS.			Thank you. The current guideline algorithm for diagnosing and managing IBS in primary care was developed based on evidence that was available at the time, including assessment of inflammatory markers. Whilst your suggestions are useful they cannot be proposed for inclusion in the guideline without a review of the necessary evidence bases and GDG consensus. The BMJ article that you have provided a link for relates to secondary care, which is outside the scope of this guideline. However your comments will be considered in subsequent reviews of this guideline.

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		(Report author Professor Tim Card.) We appreciate that one aim of the IBS Guideline was to reduce unnecessary endoscopies in IBS patients but this should be matched by a concern not to delay diagnosis of IBD. The BMJ article shows that faecal calprotectin is a useful pre-endoscopy screening test and we believe would be a useful addition to a clinical decision on referral for investigation.			
BoehrInger Ingelheim Ltd	Agree with proposal to not update				Thank you.
The Society and College of Radiographers	agree		Ultrasound does not feature in the original diagnostic recommendations.		Thank you. This will be noted for consideration by the GDG if the guideline is updated.
		It might be worth making a comment to cross-reference to the new NICE guidelines on ovarian cancer, CG122, April 2011. This is an extract from these: 1.1.1.5 Carry out appropriate tests for ovarian cancer (see section 1.1.2) in any woman of 50 or over who has experienced symptoms within the			Thank you. This will be cross referred as appropriate

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		last 12 months that suggest irritable bowel syndrome (IBS)8, because IBS rarely presents for the first time in women of this age			
British Society of Gastroenterology - Royal College of Physicians (BSG-RCP)	Agree to keep TCAs as secondline treatment	I do not think the Friedrich paper is appropriately cited – it relates to patients with IBS **and** co-morbid depression, who themselves are a minority part of the IBS population. Even in that analysis the evidence was equivocally beneficial.			Thank you. If the guideline is to be updated a full review and appraisal of the evidence will be undertaken, and cited appropriately within the context of the guideline.
British Society of Gastroenterology - Royal College of Physicians (BSG-RCP)	Disagree that the evidence in favour of biofeedback and relaxation to upgrade their recommendation	The three cited studies are in very small numbers and/or highly selected groups. A general recommendation for these therapies to a generic group of patients is not reasonable in this population.			Thank you.
British Society of Gastroenterology - Royal College of	Agree re not changing probiotic recommendation	As discussed, there is substantial evidence both supporting and denying benefit of these agents in IBS. I think it's important not to throw the baby out with the bathwater – future studies need to be recommended, focussing on IBS subgroups, as the			Thank you.

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Physicians (BSG-RCP)		studies in the “beneficial” column are generally in distinct subgroups.			
British Society of Gastroenterology - Royal College of Physicians (BSG-RCP)	Disagree with proposal not to update: Diagnosis recommendations	Despite the Title of the original Guideline, the Literature search in 2 gives no indication that evidence of improved diagnostic strategies have been recognised as a need for updating. There have been several Systematic Reviews, or Guidance Documents, from relevant organisations indicating that simple investigations identify alternative, treatable diagnoses in sizeable proportions of patients who would otherwise be classified as IBS in primary care. Calprotectin for inflammatory bowel disease, SeHCAT for bile acid diarrhoea, faecal pancreatic elastase for pancreatic insufficiency all detect diseases that can be confused with IBS, which have considerable incidence and have specific therapies. Their place alongside serological testing for coeliac disease needs addressing.			Thank you. During the review process no new literature was found in our Randomised Controlled Trial search, and none of the GDG members indicated that changes in the evidence base of diagnostics in relation to IBS had changed, thus no focused searching was performed in this area. However, SeHCAT is currently being appraised for potential review by the Medical Technology Evaluation Programme. Your comments in relation to diagnostics will be considered in subsequent reviews of the guideline.
Royal College of Nursing	Agree	We agree that the guideline does not need to be updated at this time.	Nil	Nil	Thank you.
Department of		The Department of Health has no substantive			Thank you.

Stakeholder	Agree?	Comments Please insert each new comment in a new row.	Comments on areas excluded from original scope	Comments on equality issues	
Health		comments to make, regarding this consultation.			
Pelvic Pain Support Network (PPSN)		Pleased to see the comments relating to diagnosis using Rome 111 criteria and the possibility of patients diagnosed using old criteria not having IBS. Also the role of dieticians and how this will be addressed			Thank you