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Evidence- & Value-based Solutions For Health Care
Clinical Improvement Consults, Content, Seminars, Training & Tools

"Explicit" Evidence-based Clinical Practice Guideline Resource Information

Irritable Bowel Syndrome (IBS) Guideline

Original creation date: March 2003

Updates

- 07/06: Herbal Preparations
- 04/07: Medication Withdrawal
- 06/09: ROME III Criteria (not added to algorithm but available on page 9)

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liberate ✦ illuminate ✦ simplify
inspire

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Suggestions for Using the IBS Clinical Practice Guideline Resource Information

The following guideline materials (including the algorithm, key points, notes and associated information and decision-aids) were designed primarily for primary care physicians and other clinicians who diagnose and manage IBS in adult patients.

These materials may also be useful to professionals who plan and implement clinical quality improvement projects.

It should be emphasized that although the materials may be useful "as is," we recommend that each organization create information and decision aids that meet local needs.

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These materials are not meant to replace the clinical judgment of any health care professional or establish a standard of care. The information contained in this document may not be appropriate for use in all circumstances. Decisions to utilize this information must be made by consumers and health care professionals in light of individual circumstances.

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Information & Decision Aid Contents

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VI. For You & Your Doctor: Scientific Information – About the principles and processes we used to analyze this information

Delfini Evidence and Usability Scale

Accompanying Documents

- *Delfini* Systematic Review Summaries: Brandt, Cash, Beck
- *Delfini* Implementation and Communication Tool
- *Delfini* Impact Assessment Template & Sample

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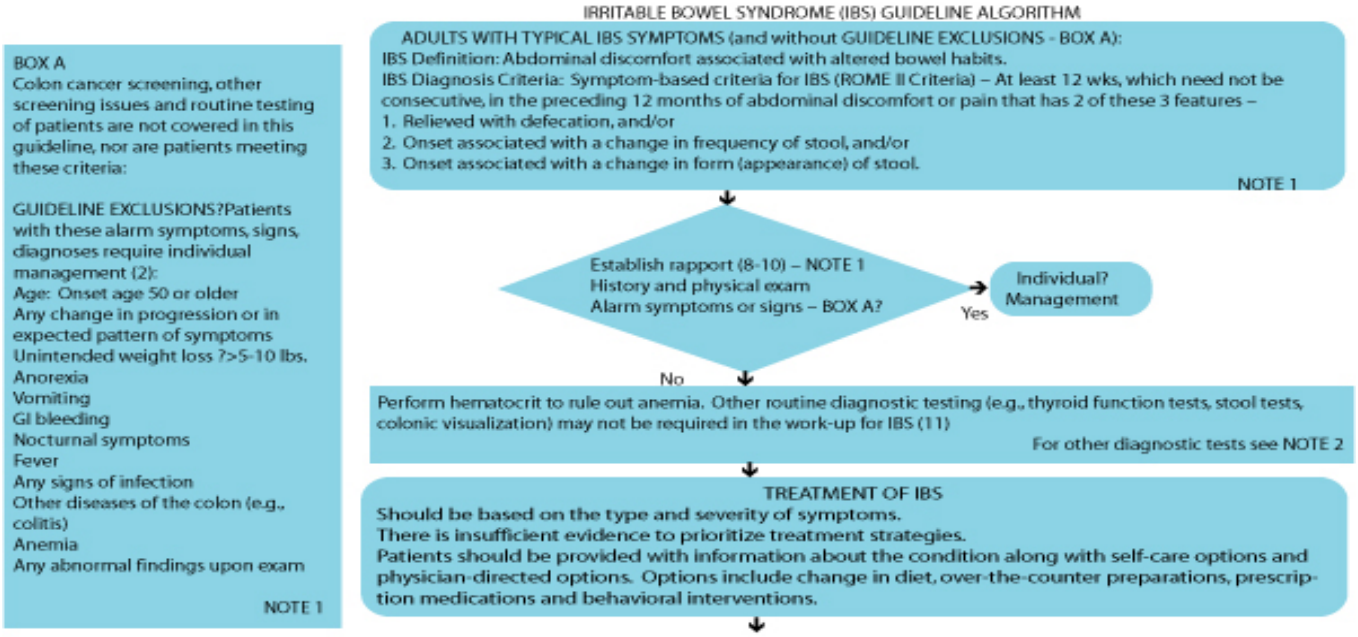

Delfini Information Quality Ratings				
●Grade A – Useful Scientific Evidence ⊙Grade B – Possibly Useful ○Grade U – Uncertain Usefulness				
Treatment Options for IBS	**Abdominal Pain**	**Constipation**	**Diarrhea**	**Gas & Bloating**
Dietary Changes	○	○	○	○
Herbal Preparations (see specifics in treatment details in IBS Information & Decision Aid)	⊙			
Bulking Agents (IBS symptoms may initially worsen) Psyllium, Wheat bran, Corn fiber, Calcium polycarbophil, Ispaghula husk	○	○	○	○
Antispasmodics (e.g. anticholinergics) Dicyclomine, Hyoscyamine	○			
Anti-diarrheals Imodium (loperamide), Lomotil (diphenoxylate hydrochloride 2.5 mg with atropine sulfate 0.025mg)			Range ⊙ to ○	
Gas-X, Mylicon (simethicone)				○
Tricyclic Antidepressants, (TCAs) e.g. – ➢ Nortriptyline (e.g., Pamelor) ➢ Desipramine (e.g., Norpramin) ➢ Amitriptyline (e.g., Elavil) ➢ Doxepin (e.g., Sinequan)	⊙	Caution is advised when using TCAs in IBS patients w/ constipation		
SSRIs (selective serotonin reuptake inhibitors) e.g. – Fluoxetine (e.g., Prozac), Paroxetine (e.g., Paxil)	○			
Serotonin Receptor Antagonists for Diarrhea Lotronex (alosetron)	● (urgency) See cautions.		●	
Behavioral Health Interventions	Grade B ⊙ for certain individual symptoms			

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Key Points Accompanying Algorithm

a. Irritable Bowel Syndrome (IBS) is defined as "abdominal discomfort associated with altered bowel habits" (2). IBS is characterized by chronic and/or recurrent symptoms which may be in combination: abdominal pain, discomfort, altered bowel habits, episodes of diarrhea and/or constipation.

b. IBS is a common condition with a **prevalence** of 10%-15% in North America.

c. There is good scientific evidence that physicians who develop good **rapport**, based on positive engagements, with IBS patients, and who provide relevant, valid and, when possible, quantitative information about management options are likely to improve patient health outcomes (8-10).

d. There is insufficient evidence to conclude that, beyond history and physical examination, any **diagnostic testing** (e.g., blood tests, stool tests, radiological or endoscopic interventions) improves patient health outcomes in patients with IBS (11).

e. In managing IBS, patients should be provided with information about the condition along with **self-care options** and **physician-directed options**. Options include change in diet, over-the-counter preparations, prescription medications and behavioral interventions. The evidence on these options varies widely.

f. Alosetron has been associated with some serious adverse events, some fatal. Be sure to carefully review the most current prescribing information on this agent.

Details about IBS management and treatment options, along with the strength of the scientific evidence for each option, are found in the accompanying ***Delfini*** **Information & Decision Aid for Adult Patients and Clinicians**.

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Algorithm Notes

These notes amplify information presented in the Irritable Bowel Syndrome (IBS) algorithm. References used in the guideline are found at the end of this document.

Delfini Validity & Usability Grading Scale for Summarizing the Evidence for Interventions

Grade of Usability	Strength of Evidence
● **Grade A:** **Useful**	The evidence is strong and appears sufficient to use in making health care decisions – it is both valid and useful (e.g., clinical significance, of sufficient magnitude, physician and patient acceptability, etc.) • Evidence from well-designed and conducted systematic reviews might fall into this category or they might be considered Grade B. Suggestion is to do a careful analysis of the review and the studies included. • Several well-designed and conducted studies that consistently show similar results o For therapy, screening, prevention and diagnostic studies: RCTs. In some cases a single, large well-designed and conducted RCT may be sufficient. o For natural history and prognosis: Cohort studies
⦿ **Grade B:** **Possibly Useful**	The evidence is potentially strong and ***might*** be sufficient to use in making health care decisions. The evidence is strong enough to conclude that the results are probably valid and useful (see above); however, study results from multiple studies are inconsistent or the studies may have some (but not lethal) threats to validity. • Evidence from well-designed and conducted systematic reviews might fall into this category or they might be considered Grade A. Suggestion is to do a careful analysis of the review and the studies included. • Evidence from at least one well-designed and conducted RCT (cohort studies for natural history and prognosis; for diagnosis, valid studies assessing test accuracy for detecting a condition when there is evidence of effectiveness from valid, applicable RCTs.)
Grade B-U: **Possible to uncertain usefulness**	The evidence might be sufficient to use in making health care decisions; however, there remains sufficient uncertainty that the evidence cannot fully reach a Grade B and the uncertainty is not great enough to fully warrant a Grade U.
○ **Grade U:** **Uncertain Validity and/or Usefulness** **Grade UA:** **Uncertainty of Author**	There is sufficient uncertainty so that caution is urged regarding its use in making health care decisions. • Uncertain Validity: This may be due to uncertain validity due to methodology (enough threats to validity to raise concern – our suggestion would be to **not** use such a study in most circumstances) or may be due to conflicting results. • Uncertain Usefulness: Or this may be due to uncertain applicability due to results (good methodology, but questions due to effect size, applicability of results when relating to biologic markers, or other issues). These latter studies may be useful and should be viewed in the context of the weight of the evidence. • Uncertain Validity and Usefulness: This is a combination of the above. • Uncertainty of Author: If the author has reached a conclusion that the findings are uncertain, doing a critical appraisal is unlikely to result in a different conclusion. The evidence leaves us uncertain regardless of whether the study is valid or not. Critical appraisal is at the discretion of the reviewer.

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Evidence Grading Recommendations for Primary Studies

Grade of Usability	Strength of Evidence
● **Grade A:** **Useful**	The evidence is strong and appears sufficient to use in making health care decisions – it is both valid and useful (e.g., clinical significance, of sufficient magnitude, physician and patient acceptability, etc.) • Study should be outstanding in design, execution and reporting with useful information to aid clinical decision-making, enabling reasonable certitude in drawing conclusions.
⦿ **Grade B:** **Possibly Useful**	The evidence is potentially strong and ***might*** be sufficient to use in making health care decisions. • Study should be of sufficient quality in design, execution and reporting with few enough threats to validity and with sufficiently useful information to aid clinical decision-making, enabling reasonable certitude in drawing conclusions.
◉ **Grade B-U:** **Possible to uncertain usefulness**	The evidence might be sufficient to use in making health care decisions; however, there remains sufficient uncertainty that the evidence cannot fully reach a Grade B and the uncertainty is not great enough to fully warrant a Grade U.
○ **Grade U:** **Uncertain Validity and/or Usefulness** **Grade UA:** **Uncertainty of Author**	There is sufficient uncertainty so that caution is urged regarding its use in making health care decisions. • Uncertain Validity: This may be due to uncertain validity due to methodology (enough threats to validity to raise concern – our suggestion would be to **not** use such a study in most circumstances) or may be due to conflicting results. • Uncertain Usefulness: Or this may be due to uncertain applicability due to results (good methodology, but questions due to effect size, applicability of results when relating to biologic markers, or other issues). These latter studies may be useful and should be viewed in the context of the weight of the evidence. • Uncertain Validity and Usefulness: This is a combination of the above. • Uncertainty of Author: If the author has reached a conclusion that the findings are uncertain, doing a critical appraisal is unlikely to result in a different conclusion. The evidence leaves us uncertain regardless of whether the study is valid or not. Critical appraisal is at the discretion of the reviewer.

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NOTE 1: Beginning Stages

- **IBS Definition and Description**
- **Criteria for Diagnosis**
- **Establishing Rapport**

IBS DEFINITION and DESCRIPTION: Evidence ⦿ Grade B – Possibly useful

IBS is a chronic medical condition characterized by symptoms of abdominal discomfort or pain and altered bowel habits. Patients can be identified by symptom-based criteria:

- **IBS alternating between diarrhea and constipation;**
- **IBS associated with abdominal discomfort, bloating and constipation;**
- **IBS associated with abdominal discomfort, fecal urgency and diarrhea (2).**

IBS is characterized by chronic and/or recurrent symptoms which may be in combination: abdominal pain, discomfort, altered bowel habits, episodes of diarrhea and/or constipation.

The abdominal discomfort in IBS is frequently described as a cramping pain, located in the lower abdomen and sometimes relieved by defecation. Patients frequently describe abdominal distention, increased gas, passage of mucous in stools, a sensation of incomplete emptying with defecation and onset associated with a change in the form of the stool.

CRITERIA FOR DIAGNOSIS: Evidence ⦿ Grade B – Possibly useful

Several groups (chart follows) have developed consensus criteria for the symptom-based diagnosis of IBS (1, 3, 4 and 5).

In a retrospective series, the Rome criteria in the absence of red flags (symptoms or signs associated with serious illness), had a sensitivity of 65%, specificity of 100%, and positive predictive value of 100% (IBS vs. organic disease). None of these patients required revision of their diagnosis during a 2-year follow-up. In a prospective study, the positive predictive value was 98% (6). The Manning Criteria have been reported to have a sensitivity for IBS of 42-90% and a specificity of 70-100% (6,7,20).

The American College of Gastroenterology (ACG) Functional Gastrointestinal Disorders Task Force recommended that physicians should use a broad definition for IBS and defined it as "abdominal discomfort associated with altered bowel habits" (1). This task force also concluded that, because the symptoms of IBS may change (e.g., from constipation alone to alternating constipation and diarrhea), IBS patients should be identified using symptom-based criteria:

- IBS alternating between diarrhea and constipation;
- IBS associated with abdominal discomfort, bloating, and constipation;
- IBS associated with abdominal discomfort, fecal urgency, and diarrhea (2).

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Symptom-based Criteria for the Diagnosis of IBS

Manning Criteria	Rome Criteria	ACG Task Force
▪ Abdominal pain relieved by defecation ▪ Looser stools with onset of pain ▪ More frequent stools with the onset of pain ▪ Abdominal distention ▪ Passage of mucous in stools ▪ Sensation of incomplete evacuation	**Rome** I ▪ At least 12 wks of continuous or recurrent symptoms of the following: ▪ **Abdominal pain or discomfort** 1. relieved with defecation, or 2. associated with a change in frequency of stool, or 3. associated with a change in consistency of stool ▪ **Two or more of the following, at least on one fourth of occasions or days:** 1. altered stool frequency, or 2. altered stool form, or 3. altered stool passage, or 4. passage of mucous, or 5. bloating or feeling of abdominal distention **Rome II** ▪ At least 12 wks, which need not be consecutive, in the preceding 12 mos. of abdominal discomfort or pain that has **two of these three features:** 1. Relieved with defecation, and/or 2. Onset associated with a change in frequency of stool, and/or 3. Onset associated with a change in form (appearance) of stool **Rome III** Recurrent abdominal pain or discomfort at least 3 days per month in the last 3 months associated with 2 or more of the following -- 1. Improvement with defecation 2. Onset associated with a change in frequency of stool 3. Onset associated with a change in form (appearance) of stool Criteria must be fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis. Discomfort is defined as an uncomfortable sensation not described as	▪ Abdominal discomfort associated with altered bowel habits ▪ Symptoms of IBS may change (e.g., from constipation alone to alternating constipation and diarrhea) and IBS patients should be identified using symptom-based criteria: 1. IBS alternating between diarrhea and constipation, or 2. IBS associated with abdominal discomfort, bloating, and constipation, or 3. IBS associated with abdominal discomfort, fecal urgency and diarrhea

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	pain. Pain or discomfort frequency is of at least 2 days a week during screening evaluation for subject eligibility for research studies. [23]	

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ESTABLISHING RAPPORT: Evidence ⦿ Grade B – Possibly useful

A good physician-patient relationship is a central issue in managing IBS. A good relationship is based on information and engagement: how information is communicated between patient and physician, and the emotional support the physician provides to the patient.

Engagement and information competencies can be learned and measured:

- Interpersonal Competence and Partnership Building: Appropriate greetings, friendly conversation, positive talk, non-judgmental attitude, inquiring about the patient's point of view (warmth, empathy, respect).
- Technical Competence: History-taking and physical exam skills.
- Providing Information: Cause of condition, seriousness, prognosis/outcome, prevention, testing, self-care, physician-directed care.
- Patient health outcomes can be improved with good physician-patient communication. Effective communication has been associated with improved emotional health, symptom resolution, physiologic measures, improved function and pain control.

Information conveyance between physician and patient is at the heart of a good physician-patient relationship:

- Information conveyed to the physician from the patient during history taking.
- Information conveyed to the patient during discussion of the nature of the condition, decision-making and during the management phase.

Emotional support appears to be equally important. Systematic reviews have been done on styles of communication including information and emotional support issues, their effects on patient satisfaction, health outcomes and adherence.

Physician-Patient Communications and Improvement in Health Outcomes

Stewart (8) found in a systematic review of 21 studies dealing with the quality of physician-patient communication and health outcomes that 16 studies reported positive associations, 4 reported non-significant results and 1 was inconclusive.

Outcomes included emotional well-being, symptom resolution, intermediate outcome measures (e.g. blood pressure), and pain control.

In the medical interview and discussion of the management plan, those physician behaviors which correlated with improved outcomes included the following ➔

- Encouraging patients to ask questions
- Enquiring about the patient's feelings
- Showing support and empathy
- Providing information and emotional support to patients during the interview
- Being willing to share decision-making
- Reaching agreement about the nature of the problem and need for follow-up

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Clinician Behaviors and Improved Outcomes

Hall, Roter and Katz (9), in a meta-analysis of 41 studies of objectively measured clinician behaviors, reported statistically significant associations between physician behaviors and satisfaction, adherence and recall as described here ➔

Satisfaction	Adherence	Patient Recall
▪ Amount of information imparted to patients ▪ Technical and interpersonal competence of physicians ▪ Partnership building ▪ Social conversation ▪ Positive talk and non-verbal communication ▪ Avoiding negative talk	▪ More information giving ▪ Fewer overall questions ▪ Positive talk (and avoiding negative talk)	▪ More information giving ▪ Partnership building ▪ Less question-asking ▪ Positive talk

These authors hypothesize that patients reciprocate socio-emotional and other behaviors and that, for patients to accept and use information provided by clinicians, clinicians must demonstrate caring and technical competence.

Verbal Behaviors by Physicians Associated with Statistically Significant Positive Patient Outcomes for Health & Patient Satisfaction

Beck (10) et al in a systematic review of physician-patient communications (verbal and non-verbal behaviors) in primary care offices reported the following significant associations between physician behavior and health outcomes or patient satisfaction. Care outcomes included satisfaction, trust, rapport, comprehension, adherence and long-term health effects (e.g., glucose control). In 14 studies meeting pre-defined criteria, the following verbal behaviors were statistically significant ➔

Verbal Behaviors
- Empathy
- Reassurance
- Friendliness
- Information sharing
- Summarizing
- Clarification
- Support
- Positive reinforcement
- Psychosocial talk

Non-verbal Communications Used by Physicians Associated with Improved Outcomes

In 8 studies of non-verbal communication, the following were associated with improved outcomes ➔

Non-Verbal Behaviors
- Head nodding
- Forward leaning
- Direct body orientation
- Uncrossed legs and arms
- Less mutual gaze

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Behaviors Used by Physicians Negatively Associated with Patient Outcomes

Beck also summarized the behaviors that have been shown in other studies to be negatively associated with patient outcomes:

Negative Behaviors	
▪ Negative social and emotional interactions ▪ Formal behavior ▪ Antagonism and passive rejection ▪ High rates of biomedical questioning ▪ Interruptions ▪ Not providing information to patient (information collection without feedback)	▪ Antagonistic behavior ▪ Directive behavior ▪ Demonstrating irritation, nervousness, anxiety or tension ▪ Dominance ▪ Directiveness

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NOTE 2
Diagnostic Testing

DIAGNOSTIC TESTING: Evidence ⦿ Grade B – Possibly useful
There is insufficient evidence to conclude that any routine diagnostic testing improves outcomes in patients with typical irritable bowel symptoms (and without alarm signs or symptoms). There is insufficient evidence to conclude that the likelihood of disease (colitis, colorectal cancer, lactose malabsorption, celiac disease, thyroid disease, infection in the gastrointestinal tract) is greater in patients with IBS than in control populations. Note: Colon cancer screening and other screening or routine testing are not addressed in this guideline.

This guideline recommends a hematocrit to R/O anemia. Recommendations for diagnostic testing of patients with suspected IBS have frequently included blood tests (e.g., CBC, thyroid function tests, tests for celiac sprue), radiologic exams (e.g., barium enema), stool tests (e.g., hemoccult testing, stool cultures or preps) or endoscopic diagnostic testing (e.g., sigmoidoscopy, colonoscopy, upper endoscopy). However, benefits of routine diagnostic testing in patients suspected of having IBS have not been demonstrated to outweigh the risks and costs. (It should be emphasized, however, that lack of evidence is not equivalent to proof of ineffectiveness.)

Basic laboratory tests are reviewed in a well-done systematic review by Cash et al. In this systematic review of patients meeting symptom-based criteria for IBS (11), six of 154 potentially relevant studies met the symptom-based criteria (Manning, Rome I, Rome II, or International Congress of Gastroenterology criteria). In these studies (average age of patients 39-56), the pretest probability of inflammatory bowel disease, colorectal cancer, or infectious diarrheas was less than 1%. The pretest probability of inflammatory bowel disease, lactose malabsorption, and thyroid dysfunction in patients with suspected IBS was similar to the prevalence of these disorders in the general population. However, the pretest probability of celiac disease in patients meeting symptom-based criteria for IBS was 10 times higher than the prevalence of celiac disease in the general population.

Conclusions

- A diagnostic evaluation is indicated if the patient has "alarm" symptoms (see Box A in algorithm) and management of these patients is beyond the scope of the guideline.
- Currently recommended diagnostic tests rarely identify organic GI disease in patients fulfilling symptom-based criteria for IBS who do not have alarm signs or symptoms. Invasive diagnostic evaluations in patients who clearly fulfill symptom-based criteria for IBS, and who do not have alarm signs or symptoms, may not be necessary.
- Patients should be made aware of this evidence and a shared decision-making process between clinician and patient should be utilized in determining whether diagnostic testing is to be performed.
    - Some patients and clinicians may derive reassurance from knowing a diagnostic evaluation has ruled out organic disease.
    - Others may wish to undergo basic laboratory testing, but not radiologic or endoscopic procedures because benefits have not been demonstrated to outweigh harms. (The incidence of colon perforation in one study was found to be 1.96/1000 colonoscopies and 0.88/1000 sigmoidoscopies (21).
    - Some patients may choose to undergo no diagnostic testing other than a hematocrit to rule out anemia.

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References

1. Evidence-based position statement on the management of irritable bowel syndrome in North America. *Am J Gastroenterol.* 2002 Nov;97(11 Suppl):S1-5).
2. Brandt LJ, Bjorkman D, Fennerty MB et al. Systematic review on the management of irritable bowel syndrome in North America. *Am J Gastroenterol*. 2002 Nov;97(11 Suppl):S7-26).
3. Manning AP, Thompson WG, Heaton KW, Morris AF. Towards positive diagnosis of the irritable bowel. *Br Med J*. 1978 Sep 2;2(6138):653-4.
4. Thompson WG, Irvine EJ, Pare P et al. Functional gastrointestinal disorders in Canada: first population-based survey using Rome II criteria with suggestions for improving the questionnaire. Dig Dis Sci. 2002 Jan;47(1):225-35.
5. Olden KW. Diagnosis of irritable bowel syndrome. Gastroenterology 2002 May;122(6):1701-14.
6. Vanner SJ, Depew WT, Paterson WG, et al. Predictive value of the Rome criteria for diagnosing the irritable bowel syndrome.Am J Gastroenterol. 1999 Oct;94(10):2912-7.
7. Chey WD, Olden K, Carter E et al. Utility of the Rome I and Rome II criteria for irritable bowel syndrome in U.S. women. Am J Gastroenterol 2002 Nov;97(11):2803-11.
8. Stewart MA. Effective Physician-Patient Communication and Health Outcomes: A Review *CMAJ* 1995.152:1423-1433.
9. Hall JA; Roter DL; Katz NR. Meta-analysis of correlates of provider behavior in medical encounters. *Medical Care*;1988, 26:657-675.
10. Beck RS, Daughtridge R, Sloane PD. Physician-Patient Communication in the Primary Care Office: A Systematic Review. *JABFP* 2002. 15:25-38. The Journal of the American Board of Family Practice
11. Cash BD, Schoenfeld P, Chey WD. The utility of diagnostic tests in irritable bowel syndrome patients: a systematic review. *Am J Gastroenterol.* 2002 Nov;97(11):2812-9.
12. Sanders DS, Carter MJ, Hurlstone DP, et al. Association of adult coeliac disease with irritable bowel syndrome: A case-control study in patients fulfilling the ROME II criteria referred to secondary care. *Lancet* 2001;358:1504-8.
13. Camilleri, M, Chey, WY, Mayer, EA, et al. A randomized controlled clinical trial of the serotonin type 3 receptor antagonist alosetron in women with diarrhea-predominant irritable bowel syndrome. *Arch Intern Med* 2001; 161:1733.
14. Drossman DA, Whitehead WE, Camilleri M. Irritable bowel syndrome: a technical review for practice guideline development. *Gastroenterology* 1997 Jun;112(6):2120-37.
15. Mitchell CM, Drossman DA. Survey of the AGA membership relating to patients with functional gastrointestinal disorders. *Gastroenterology*. 1987 May;92(5 Pt 1):1282-4.
16. Friedman, G. Diet and the irritable bowel syndrome. *Gastroenterol Clin North Am* 1991; 20:313.
17. Kaplan MA, Prior MJ, Ash RR et al. Loperamide-simethicone vs loperamide alone, simethicone alone, and placebo in the treatment of acute diarrhea with gas-related abdominal discomfort. A randomized controlled trial. *Arch Fam Med* 1999 May-Jun;8(3):243-8.

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18. Lustman F, Walters EG, Shroff NE, et al. Diphenoxylate hydrochloride (Lomotil) in the treatment of acute diarrhoea. *Br J Clin Pract.* 1987 Mar;41(3):648-51.
19. Harford WV, Krejs GJ, Santa Ana CA et al. Acute effect of diphenoxylate with atropine (Lomotil) in patients with chronic diarrhea and fecal incontinence. *Gastroenterology*. 1980 Mar;78(3):440-3.
20. Talley NJ, Phillips SF, Mulvihill C et al. Diagnostic value of the Manning criteria in irritable bowel syndrome. *Gut* 1990 Jan:31 (1):77-81.
21. Gatto NM, Frucht H, Sundararajan V, et al. Risk of Perforation After Colonoscopy and Sigmoidoscopy: A Population-based Study. J Natl Cancer Inst 2003; 95:230-6.
22. Madisch A, Holtmann G, Plein K, Hotz J. Treatment of irritable bowel syndrome with herbal preparations: results of a double-blind, randomized, placebo-controlled, multi-centre trial. Aliment Pharmacol Ther 2004; 19: 271–279.
23. Longstreth GF, Thompson WG, Chey WD, Houghton LA, Mearin F, Spiller RC. Functional bowel disorders. Gastroenterology. 2006 Apr;130(5):1480-91. PMID: 16678561

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Guideline Documentation

Introduction, Background and Scope of the Irritable Bowel Syndrome (IBS) Guideline: Irritable Bowel Syndrome (IBS) is defined as "abdominal discomfort associated with altered bowel habits"(2). IBS is a common condition with a prevalence of 10%-15% in North America and frequently causes a significant decrease in quality of life. **Go to the Algorithm to see Guideline Exclusions and Notes**.

Experts, published papers and textbooks vary widely in their recommendations regarding diagnostic testing and management of IBS. The objective of this explicit, evidence-based clinical guideline is to assist clinicians, patients and others who have uncertainty and knowledge gaps in the areas of diagnosis and management of IBS to better understand the current best-available evidence regarding IBS and to improve their management of uncomplicated IBS.

The Impact Assessment Template included in this resource kit is an optional, customizable aid designed to help health care organizations reflect upon their current care practices for IBS and to assist with projecting potential changes in quality of life, satisfaction and cost resulting from successful local implementation of the guideline. This tool is meant only to give organizations ideas for how they might approach assessing costs and other changes. If the template will be used directly to input organizational data, it is highly recommended that modifications be made by a staff person experienced both in Excel and in creating formulas. Any computations resulting from changes should be examined closely for accuracy.

Guideline Development Team

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Guideline Development Process: An "explicit" evidence-based process using the 4 "A"s (Ask • Acquire • Appraise • Apply) was used to develop this clinical guideline during March 2003; additions were made on 07/06 for herbal preparations, and 04/07 due to a medication withdrawal from market.:

- **Ask:** Questions regarding natural history, prognosis, diagnosis, non-drug and drug therapy, and follow-up were addressed to the medical literature (see **Search Strategy** below).

- **Acquire/Appraise:** Studies were filtered excluding case series, editorials and opinions. Meta-analyses and systematic reviews without lethal threats to validity were prioritized and utilized when possible. RCTs were used when published subsequent to systematic reviews or when systematic reviews were not available. The evidence was evaluated for relevance and internal validity, and evidence summary documents were developed for the best available evidence.

- **An evidence grading methodology** was used to filter and grade the evidence for validity and usability. See **Guideline Notes** and also *Delfini* **Information & Decision Aid for Patients and Practitioners.**

- **Guideline recommendations** were based on systematic reviews, and RCTs when available, but expert opinion was utilized in parts of the guideline when evidence was not available or not usable because of threats to validity.

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The strength of the evidence is noted in the guideline and decision support.

- **Guideline Decision-Making Process**: All decisions were made by consensus using the best-available evidence along with expert opinion when evidence was not sufficient to guide recommendations.

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- **Guideline Peer Review**: The guideline was reviewed for relevance and validity by –
  - David Bjorkman MD, MSPH, SM, Professor of Medicine, University of Utah School of Medicine
  - Walter Peterson, MD, Professor of Medicine, University of Texas Southwestern School of Medicine and co-editor of Alimentary Pharmacology and Therapeutics
  - Following guideline development, we also invited comments from a gastroenterologist medical director at Novartis and accepted those changes we independently deemed to be guideline improvements
  - We are also grateful to various medical leaders and other participants of the community practice meetings who contributed their input and made suggestions.

Funding: ***Delfini* Group, LLC**, was invited by Novartis to independently develop an evidence-based clinical guideline. Prior to agreeing, and at risk without compensation, ***Delfini*** first evaluated the evidence available for IBS, basing a decision to proceed only upon meeting rigorous requirements 1) that there be sufficient valid and relevant evidence available, 2) that there be sufficiently important results (e.g., statistical significance, clinical relevance and patient-centeredness), and 3) which ***Delfini*** agreed would be a guideline worth developing, irrespective of any remuneration. This guideline is based on the principles and rigorous, systematic methods for "explicit" evidence-based guidelines first conceptualized by David Eddy, MD, PhD, and subsequently operationalized and used by Dr. Michael Stuart during his career at Group Health Cooperative in Seattle, Washington. ***Delfini*** has licensed this guideline to Novartis Pharmaceuticals, manufacturer of Zelnorm (tegaserod).

Potential Conflicts of Interest: See **Funding**. We believe this guideline has been developed with no conflict of interest and stand fully behind it based on precepts of the most rigorous practice of evidence-based medicine and the "explicit" guideline development method. Even when basing recommendation on evidence-based medicine principles, a great deal of judgment is necessary. This method is highly transparent, aiding in reproducibility, validity assessment and evaluation, and as such, this method is an aid to expected differences in judgment.

We believe our biases are toward critically appraised evidence with meaningful results and toward patient-centeredness. We believe that "value" and other issues should generally be assessed locally due to variations in local circumstances and also because we believe patients should have information about evidence-based options regardless of coverage.

We believe the guideline, itself, supports our evidence and patient-centered approach:

1. We believe our process is highly transparent, and it is fully documented for replicability.
2. The evidence stands on own and is available to others for review.
3. We have demonstrated our preference for first trying low risk/low cost options despite lack of high quality evidence.
4. We have attempted to present information in a fair and balanced way (averaging NNTs for example).
5. While at Group Health, Dr. Stuart implemented a guideline which significantly decreased the use of diagnostic testing where there was no good evidence for such testing. Hence the recommendations in this guideline are consistent with his past approach.
6. Much of the language used in the guideline and decision support is identical to, or consistent with, language we have previously used in similar work that is unfunded – and which we make publicly available.

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7. We have demonstrated our preference for a conservative approach to drug use, consistent with our approach for similar, unfunded work.

Search Strategies: The National Library of Medicine (PubMed, OVID) were searched from 1970-Feb, 2003 using the search terms listed below. Search Limits and Clinical Queries in PubMed were utilized. Bibliographies were hand-searched.

Natural History, Prognosis: Search strategy included combinations: MeSH Terms, Epidemiology, Etiology, Language, and Text Word, colonic diseases, functional, irritable bowel syndrome, adult, colonic diseases, Meta-Analysis, English, Practice Guideline, Systematic Review.

Diagnosis: Search strategy included combinations: MeSH Terms, Text Word, colonic diseases, functional, irritable bowel syndrome, Meta-Analysis, English, adult, Practice Guideline, diagnosis, systematic review, blood, parasite, stool analysis, radiography, hydrogen breath testing, thyroid function, sedimentation rate, endoscopy, barium enema, colonoscopy, flexible sigmoidoscopy.

Management, Follow-up, Therapy: Search strategy included combinations: MeSH Terms, Text Words, clinical trial, randomized, Meta-Analysis, English, adult, Diet Therapy, Drug Therapy, Therapy, Colonic Diseases, Practice Guideline, self-management, systematic review, communication, bedside manner, rapport, physician-patient relationship, medical interview, adherence, understanding, patient-understanding, compliance, satisfaction, antispasmodic, antimuscarinic, diet, smooth muscle relaxant, dicyclomine, hyoscyamine, constipation, fiber, polycarbophil, bulking agents, laxative, antidepressant, tricyclic antidepressant, tegaserod, alosetron, antidiarrheal agents, loperamide, lomotil, simethicone, behavioral therapy, colonic diseases, functional , irritable bowel syndrome.

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