Complete Summary

GUIDELINE TITLE

Initial management of dyspepsia and GERD.

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Initial management of dyspepsia and GERD. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2006 Jul. 53 p. [100 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Dyspepsia and GERD. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2004 Jul. 50 p.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- May 2, 2007, Antidepressant drugs: Update to the existing black box warning on the prescribing information on all antidepressant medications to include warnings about the increased risks of suicidal thinking and behavior in young adults ages 18 to 24 years old during the first one to two months of treatment.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **
SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

- Dyspepsia, including gastric ulcer dyspepsia; duodenal ulcer dyspepsia; or non-ulcer (functional) dyspepsia
- Gastroesophageal reflux disease (GERD)

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Family Practice
Gastroenterology
Internal Medicine
Radiology

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To increase the use of recommended methods for evaluating dyspepsia
- To increase appropriate pharmaceutical treatment of patients with dyspepsia
- To decrease complications associated with peptic ulcer disease
- To improve functional outcomes and satisfaction of patients with dyspepsia
- To increase the use of initial treatment recommendations for evaluating gastroesophageal reflux disease (GERD)
- To increase appropriate treatment for patients who have ongoing symptoms after initial treatment recommendations

TARGET POPULATION

Adult males and non-pregnant adult females with symptoms of epigastric pain or discomfort on greater than 25% of days over the past 4 weeks. Individuals with nausea, heartburn or acid regurgitation are eligible .This guideline does not

stipulate the exact symptoms that define dyspepsia, thus allowing the clinician some latitude in identifying the patients to whom this guideline can be applied.

Patients with atypical symptoms (e.g., laryngopharyngeal reflux [LPR], odynophagia, water brash, globus sensation, laryngitis, chronic cough, asthma, and chest pain) are not covered in this guideline but may be included if either heartburn or regurgitation are the primary presenting symptoms.

This guideline does not apply to patients whose symptoms are characteristic of biliary tract disease, pancreatic disease, or irritable bowel syndrome.

INTERVENTIONS AND PRACTICES CONSIDERED

Dyspepsia

Diagnostic Assessment

1. Medical history including history of prior documented ulcer
2. Evaluate symptoms, with particular attention to presence of alarm features
3. Endoscopy
4. Multiphase upper gastrointestinal (UGI) studies
5. *Helicobacter pylori (H. pylori)* testing (stool antigen, serology, or urea breath testing [UBT])
6. Evaluation for increased risk of gastric cancer
7. Biopsy for *H. pylori*

Treatment

1. Eradicative therapy for *H. pylori* consisting of proton pump inhibitor (PPI) in combination with other drugs, including antibiotics (e.g., clarithromycin, amoxicillin, tetracycline, metronidazole) and bismuth
2. Acid suppression with full-dose PPI in absence of *H. pylori*
3. Discontinuation of nonsteroidal anti-inflammatory drugs
4. Smoking cessation
5. Referral to gastroenterology for refractory cases

Gastroesophageal Reflux Disease (GERD)

Diagnostic Assessment

1. Flexible esophagogastroduodenoscopy
2. 24-hour pH monitoring

Treatment

1. Behavioral/lifestyle modifications
    - Dietary changes (avoid caffeine, chocolate, fats, alcohol, decaffeinated tea and coffee, caffeinated soft drinks, citrus juices, peppermint, and spearmint)
    - Weight loss
    - Avoiding large meals

    - Body positioning (avoid lying down after eating, elevating head of bed)
    - Tobacco cessation
2. Changing medications that can lower the lower esophageal sphincter (LES), such as theophylline, calcium channel blockers, and barbiturates
3. Use of antacids and over-the-counter PPIs
4. Step-down therapy
5. PPIs or histamine-2-receptor antagonists for patients with refractory reflux

MAJOR OUTCOMES CONSIDERED

- Efficacy of *Helicobacter pylori* testing (positive or negative)
- Sensitivity, specificity, positive and negative predictive value of diagnostic instruments
- Efficacy/side effects of medications
- Recurrence of peptic ulcer disease
- Recurrence of esophagitis
- Incidence and risk factors of gastric cancer
- Healing rates
- Costs of diagnostic tests and treatments

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system presented below, and are designated as positive, negative, or neutral to reflect the study quality.

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

Study Quality Designations:

The quality of the primary research reports and systematic reviews are designated in the following ways on the conclusion grading worksheets:

Positive: indicates that the report or review has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.

Negative: indicates that these issues (inclusion/exclusion, bias, generalizability, and data collection and analysis) have not been adequately addressed.

Neutral: indicates that the report or review is neither exceptionally strong nor exceptionally weak.

Not Applicable: indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

Classes of Research Reports:

A. Primary Reports of New Data Collection:

   Class A:

   - Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Nonrandomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Helicobacter pylori testing without endoscopy, followed by eradication treatment for patients with positive results is a cost-effective approach for initial long-term management of dyspepsia. (See Conclusion Grading Worksheet C – Annotation #10 in the original guideline document).

Additional cost-benefit analyses have been reviewed, including analyses of initial endoscopy and proton pump inhibitors. Refer to the original guideline document for details.

METHOD OF GUIDELINE VALIDATION

Clinical Validation-Pilot Testing
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Institute Partners: System-Wide Review

The guideline draft, discussion, and measurement specification documents undergo thorough review. Written comments are solicited from clinical, measurement, and management experts from within the member medical groups during an eight-week period of "Critical Review."

Each of the Institute's participating medical groups determines its own process for distributing the guideline and obtaining feedback. Clinicians are asked to suggest modifications based on their understanding of the clinical literature coupled with their clinical expertise. Representatives from all departments involved in implementation and measurement review the guideline to determine its operational impact. Measurement specifications for selected measures are developed by the Institute for Clinical Systems Improvement (ICSI) in collaboration with participating medical groups following general implementation of the guideline. The specifications suggest approaches to operationalizing the measure.

Guideline Work Group: Second Draft

Following the completion of the "Critical Review" period, the guideline work group meets 1 to 2 times to review the input received. The original guideline is revised as necessary, and a written response is prepared to address each of the suggestions received from medical groups. Two members of the Preventive Services Steering Committee carefully review the Critical Review input, the work group responses, and the revised draft of the guideline. They report to the entire committee their assessment of two questions: (1) Have the concerns of the medical groups been adequately addressed? (2) Are the medical groups willing and able to implement the guideline? The committee then either approves the guideline for pilot testing as submitted or negotiates changes with the work group representative present at the meeting.

Pilot Test

Medical groups introduce the guideline at pilot sites, providing training to the clinical staff and incorporating it into the organization's scheduling, computer, and other practice systems. Evaluation and assessment occurs throughout the pilot test phase, which usually lasts for three months. Comments and suggestions are solicited in the same manner as used during the "Critical Review" phase.

The guideline work group meets to review the pilot sites' experiences and makes the necessary revisions to the guideline, and the Preventive Services Steering Committee reviews the revised guideline and approves it for implementation.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC) and the Institute for Clinical Systems Improvement (ICSI): In addition to updating their clinical guidance, ICSI has developed a new format for all guidelines. Key additions and changes include: combination of the annotation and discussion section; the addition of "Key Points" at the beginning of most annotations; the inclusion of references supporting the recommendations; and a complete list of references in the Supporting Evidence section of the guideline. For a description of what has changed since the previous version of this guidance, refer to Summary of Changes – July 2006.

The recommendations for the management of dyspepsia are presented in the form of a primary algorithm, Dyspepsia, with 21 components, and a secondary algorithm, Gastroesophageal Reflux Disease (GERD), with an additional 13 components (for a total of 34 components), accompanied by detailed annotations. Clinical highlights and selected annotations (numbered to correspond with the algorithm) follow.

Class of evidence (A-D, M, R, X) and conclusion grade (I-III and Not Assignable) definitions are repeated at the end of the "Major Recommendations" field.

Clinical Highlights

- Send patients with dyspepsia plus one of the following alarm features for urgent endoscopic evaluation. Suggested time frames for the urgency of endoscopy are provided with each of the alarm features listed. (*Annotations #3, 4*)
    - Melena (*within 1 day if ill*)
    - Hematemesis (*within 1 day if ill*)
    - Persistent vomiting (*7-10 days*)
    - Anemia (*7-10 days*)
    - Acute onset of total dysphagia (*within 1 day*)
    - Weight loss greater than 5% (involuntary) (*7-10 days*)
- Patients 55 years of age and older with symptoms of uncomplicated dyspepsia should be evaluated with nonurgent upper endoscopy. (*Annotation #8*)

- Patients with dyspepsia, but no alarm features or reflux symptoms, should receive *Helicobacter pylori* testing and if positive, eradicative therapy. (*Annotations #5, 6, 10, 11*)
- Stool antigen is the preferred test for *H. pylori* in uninvestigated dyspepsia. (*Annotation #6*)
- Patients with dyspepsia and negative testing results for *H. pylori* should be treated empirically with proton pump inhibitors (PPIs). (*Annotation #12*)
- Patients age 50 or older and who have had symptoms of GERD for 10 years or more should be considered for endoscopy during initial management. (*Annotation #25*)
- Patients with gastroesophageal reflux should receive single trial step-down therapy. (*Annotations #25, 29, 30, 31, 34*)
- Patients with GERD usually require long-term PPI therapy. (*Annotation #34*)
- Patients with GERD usually do not require *H. pylori* testing. (*Annotation #34*)

Dyspepsia Algorithm Annotations

1. **Symptoms of Dyspepsia or GERD**

   Key Points:

   - Dyspepsia is defined as pain or discomfort felt to arise in the upper gastrointestinal tract with symptoms on greater than 25% of the days over the past four weeks.
   - GERD is the probable diagnosis if the patient has heartburn (retrosternal pain) or acid regurgitation (a sour or bitter taste in mouth) as the dominant symptom.

   Dyspepsia

   This guideline does not stipulate the exact symptoms that define dyspepsia, thus allowing the clinician some latitude in identifying the patients to whom this guideline can be applied.

   In this guideline, dyspepsia is defined as pain or discomfort felt to arise in the upper gastrointestinal (GI) tract with symptoms on greater than 25% of days over the past 4 weeks. Patients with epigastric pain or discomfort, or nausea are eligible. The emphasis is on pain or discomfort which is present in the epigastrium. The upper GI tract includes the stomach, distal esophagus and proximal duodenum. Patients should have symptoms at least seven days a month. This guideline should not be applied to patients with symptoms that are occasional (i.e., one day a week or less) or acute (i.e., present less than one week). However, patients with symptoms every day for seven days are eligible. Most of the patients will have symptoms which the clinician feels are suspicious for either peptic ulcer disease (PUD) or gastroesophageal reflux disease (GERD).

   Many other conditions may present with upper abdominal pain. This guideline should not be applied to patients in whom the clinician is suspicious of biliary tract disease or pancreatic disease. Thus, patients with right upper quadrant pain, inter-scapular pain, or pain that radiates straight through to the back

should not be included. Similarly, patients with fever, jaundice, pruritis or other signs of biliary obstruction should not be included.

Irritable bowel syndrome (IBS) is a common condition which may manifest as upper abdominal pain. Like dyspepsia, IBS represents a constellation of symptoms. An international panel of experts defined IBS as chronic or recurrent abdominal pain, relieved by defecation or associated with a change in the frequency or consistency of stool.

Many patients who meet the definition of dyspepsia will also meet the definition of IBS. Physicians should use discretion in utilizing this guideline. Patients with typical IBS symptoms and minimal upper gut symptoms should not be included, whereas patients with typical dyspepsia and minimal bowel complaints should be included. Patients with significant overlap should be included if the dyspepsia symptoms are the primary reason for the patient to seek medical care.

GERD

GERD is the probable diagnosis if the patient has heartburn (retrosternal pain) or acid regurgitation (a sour or bitter taste in mouth) as the dominant symptom. These symptoms are sought because their presence is associated with a probability of 89% and 95%, respectively, of GERD based on studies using esophageal pH monitoring as the reference standard. The goal is to minimize the number of patients with ulcer referred to the GERD algorithm.

In this guideline, the focus is on the most prominent symptoms of heartburn and acid regurgitation. Atypical manifestations such as laryngopharyngeal reflux (LPR), odynophagia, water brash, globus sensation, laryngitis, chronic cough, asthma and chest pain are other possible presentations. With some of these symptoms their causes could be multiple and there is some controversy as to the role GERD plays. Patients with these symptoms may be included if either heartburn or regurgitation are the primary presenting symptoms, but providers clinical judgment should be used.

Evidence supporting this recommendation is of classes: C, R

3. **Are There Alarm Features?**

Alarm features should be sought in all patients presenting with dyspepsia. If alarm features are present, endoscopy should be performed (suggested time frames for urgency of endoscopy are provided with each of the alarm features listed). Alarm features is a term that is used frequently in the dyspepsia literature to describe clinical features that may suggest underlying disease that should be diagnosed and treated without the delay of an empiric therapeutic trial. Alarm features frequently cited are:

- Anemia (*7-10 days*)
- Acute onset dysphagia (*within 1 day*)
- Hematemesis (*within 1 day if ill*)
- Melena (*within 1 day if ill*)

- Persistent vomiting (*7-10 days*)
- Weight loss greater than 5% (involuntary) (*7-10 days*)

Evidence supporting this recommendation is of class: D

4. **Endoscopy for Alarm Features/Out of Guideline**

Key Points:

- Patients with alarm features need urgent endoscopic evaluation.

Endoscopy is the procedure of choice for evaluation of dyspepsia. A single contrast barium study is not an acceptable alternative. Multiphase upper gastrointestinal (UGI) studies performed by radiologists with specific training in gastrointestinal radiology are an acceptable alternative to endoscopy. In some settings endoscopy may be done by a general surgeon.

If specialty radiologic expertise with multiphase barium UGI is available, UGI study should be viewed as an alternative to endoscopy. Otherwise, endoscopy provides greater sensitivity for the diagnosis of peptic ulcer disease. [*Conclusion Grade III: See Conclusion Grading Worksheet A - of the original guideline document - Annotation #4 (Endoscopy)*].

Evidence supporting this recommendation is of classes: A, C

5. **Prior Documented Ulcer?**

In patients presenting with dyspepsia and a prior documented ulcer, referral to either a gastroenterologist or direct-access endoscopy is appropriate. Documentation of the prior ulcer must include an endoscopy or barium UGI report confirming the presence of an ulcer.

6. ***H. pylori* Testing, Eradication/Case Management**

Key Point:

- Testing and treatment of *H. pylori* is the cornerstone of the management of peptic ulcer disease.
- Maintenance PPI treatment is not indicated for those experiencing symptom resolution after treatment. Patients with complicated peptic ulcer disease may be considered for maintenance treatment using PPI at one-half the therapeutic dose after successful treatment.
- Documenting *H. pylori* eradication should be limited to those with a history of complicated peptic ulcer disease.

Case management should begin with *H. pylori* testing. Several tests are available with different sensitivity, specificity, and costs (refer to the "Diagnostic Tests for *Helicobacter Pylori*" Table in the original guideline document). Those who are positive should receive eradicative therapy. (Refer to Main Algorithm Annotation #10, "Is *H. pylori* Infection Present?" and Annotation #11, "Treatment for *H. pylori*.").

Stool antigen is now the non-invasive office test of choice due to its high positive likelihood ratio (LR) over serologic testing. Stool antigen can also be used as a test of cure while serology cannot.

Recall that the patient must discontinue PPI for 2 weeks for Urea Breath Test (UBT) and stool antigen testing.

Patients who continue nonsteroidal anti-inflammatory drugs (NSAIDs) during treatment for peptic ulcers should have the duration of PPI treatment extended to twelve weeks total.

Symptoms continuing for a month or more into treatment should prompt endoscopy regardless of initial treatment. Further evaluation may be necessary.

Maintenance PPI treatment is not indicated for those experiencing symptom resolution after treatment. Patients with complicated peptic ulcer disease may be considered for maintenance treatment using PPI at one-half the therapeutic dose after successful treatment. Documenting *H. pylori* eradication should be limited to those with a history of complicated peptic ulcer disease.

Evidence supporting this recommendation is of classes: A, C, D, M, R

8. **Is Patient Age 55 or Older, or at Increased Risk of Gastric Cancer?**

Key Points:

- A small number of patients presenting with dyspepsia will have gastric cancer.
- When treating an immigrant population from East Asia and East Europe, the higher risk of gastric cancer may be considered an alarm feature prompting early endoscopy.

Environmental and genetic factors along with a number of disorders are associated with an increased risk of gastric cancer. The precursor conditions associated with increased risk for gastric cancer include chronic atrophic gastritis and intestinal metaplasia, pernicious anemia, benign gastric ulcer disease, *H. pylori* infection, Menetrier's disease, gastric adenomatous polyps, immunodeficiency syndromes, and Barrett's esophagus.

Genetic and environmental factors for an increased risk of gastric cancer include a family history of gastric cancer, blood type A, hereditary nonpolyposis colon cancer syndrome, low consumption of fruits and vegetables, consumption of salted, smoked, or poorly preserved foods, cigarette smoking, alcohol use, and obesity.

Esophagogastroduodenoscopy, performed within 4 weeks, may be appropriate in patients age 55 or over who have no obvious environmental and genetic risks because the incidence of gastric cancer is increased, but no study to date has shown improved outcomes. [*Conclusion Grade II: See Conclusion*

Grading Worksheet B of the original guideline document - Annotation #8 (Esophagogastroduodenoscopy)].

Initial endoscopy may be cost-effective in this age group; however, sensitivity analysis shows the cost effectiveness is driven by the cost of endoscopy and so will vary.

Evidence supporting this recommendation is of classes: A, C, D

10. **Is *H. pylori* Infection Present?**

Key Points:

- In most patients with dyspepsia, testing for *H. pylori* infection is the first step.

An approach to possible gastric or duodenal ulcer disease should include a strategy to eliminate *H. pylori*. Sensitive and specific point-of-care testing is commercially available and can provide 5 to 10 minute turnaround using whole blood, serum, or plasma. *H. pylori* urea breath testing (UBT) has similar sensitivity and superior specificity. If the cost and availability of UBT is similar to serology in the local practice environment, it would be the preferred test.

H. pylori testing without endoscopy, followed by eradication treatment for patients with positive results, is a cost-effective approach for initial long-term management of dyspepsia. [*Conclusion Grade II: See Conclusion Grading Worksheet C- of the original guideline document, - Annotation #10 (H. Pylori Testing)*]

The UBT is the test of choice in those situations where post-treatment testing is required. Post-treatment testing is not generally recommended. This testing may however be indicated in selected patients with complicated ulcer disease, low-grade gastric mucosa associated lymphoid tissue (MALT) lymphoma and following resection of early gastric cancer.

If testing is performed for eradication, it should be delayed at least 4 weeks after the completion of therapy and/or the use of proton pump inhibitors. This permits a differentiation between suppression and eradication of H. pylori. Serology is not useful in this situation as antibody levels commonly remain elevated for months to years after successful treatment.

Evidence supporting this recommendation is of classes: A, C, M, R

11. **Treatment for *H. pylori***

Key Points:

- Many regimens are effective in treating *H. pylori*. However, all regimens require more than one drug.

There are multiple regimens U.S. Food and Drug Administration (FDA) approved for treatment of *H. Pylori*. In addition, many more are published in the literature. The two therapies listed in the original guideline document are equally effective in eradicating *H. pylori* (95% effective) and in preventing gastrointestinal ulcer recurrence (80% effective). These two therapies represent a combination of ease of adherence and cost. Patient adherence is very important. The patient can and should take all drugs simultaneously. The choice of regimen may be influenced by frequency of dosing or patient tolerance or highly variable local acquisition costs.

Regardless of which therapy course is chosen, patients with significant symptoms at presentation may continue to use a standard dose of a PPI for 3 extra weeks at the end of the combination drug treatment. The optimal rates of eradication are obtained within 14-day dosing but 7-day dosing are almost similar.

See the original guideline document for examples of two treatment therapies with specific 7- to 14-day dosing.

12. **Empiric Trial of Full Dose PPI/Address NSAID Use**

Key Points:

- Patients without *H. pylori* should receive acid-suppression therapy to block acids.
- Dyspeptic patients may have peptic ulcers even if testing for *H. pylori* is negative. A symptomatic response to 4 weeks of PPI suggests that an 8 to 12 week course of PPI may be curative. If aspirin or NSAIDs can't be stopped, the odds of a response to a PPI and the rapidity of that response are increased.

Empiric Trial

The available delayed-release proton pump inhibitors (PPIs – omeprazole, esomeprazole, lansoprazole, pantoprazole, rabeprazole) appear to be equivalent in efficacy in the management of acid-peptic disorders when given in equipotent acid-suppressive doses. Adverse event profiles for these delayed-release formulations are also similar. Full-dose therapy for four weeks as an empiric trial is recommended.

Please refer to the original guideline document for generic names, trade names and dosing suggestions of proton pump inhibitors (PPI).

NSAIDs

Patients on nonsteroidal anti-inflammatory drugs (NSAIDs)

Patients on NSAIDs should have these discontinued if possible. If it is not possible to discontinue NSAIDs, a duration of PPI therapy of 12 weeks is recommended. This recommendation is based on well documented higher healing rates in patients with gastric as well as duodenal ulcers treated for a

duration of twelve weeks compared to eight weeks. (See also Main Algorithm Annotation #17 "Case Management/Out of Guideline").

Evidence supporting this recommendation is of classes: A, D, R

13. **Symptoms Persist >4 Weeks?**

Although ulcer healing may take 8 weeks or more, the majority of patients with a gastric or duodenal ulcer have improvement in symptoms at 4 weeks. Moreover, study shows that the yield of esophagogastroduodenoscopy is improved by limiting evaluation to those with persistent symptoms persisting despite a short course of therapy.

Evidence supporting this recommendation is of classes: A, D

14. **Management of Symptomatic Relapse**

Dyspepsia often comes and goes. Some patients will experience recurrent symptoms despite symptom resolution with the initial management. In past guidelines, these patients were referred for endoscopy primarily to exclude the possibility of cancer. However, the diagnostic yield of endoscopy in this situation is low. Patients who are thought to be at very low risk of gastric cancer (based primarily on younger age) may be managed without endoscopy. If the patient had an *H. pylori* infection previously (Annotation #10, "Is *H. pylori* Infection Present?") then testing for eradication with either a stool antigen test or a breath test would be reasonable. If persistent *H. pylori* infection is identified, then retreatment with a regimen different from the regimen used earlier (Annotation #11, "Treatment for *H. pylori*") would be appropriate. If the patient was *H. pylori* negative either at time of initial management or at the time of the testing of eradication then another trial of acid suppression could be considered (Annotation #12, "Empiric Trial of Full Dose PPI/Address NSAID Use"). If symptoms resolve, no further care is necessary. If symptoms persist then an endoscopy should be considered.

Evidence supporting this recommendation is of class: X

16. **Endoscopy Positive?**

Endoscopy is the procedure of choice in most situations for evaluation of dyspepsia. If an ulcer is seen, a biopsy for *H. pylori* should be taken. A single contrast barium study is not an acceptable alternative. Multiphasic UGI studies performed by radiologists with specific training in gastrointestinal radiology are an acceptable alternative to endoscopy.

17. **Case Management/Out of Guideline**

Patients with an ulcer should have an *H. pylori* breath test if their stomach was not biopsied at the time of endoscopy. Treatment to eradicate *H. pylori* should be provided to those infected. If previously treated for *H. pylori*, a different regimen should be used and provided. Metronidazole should be substituted for amoxicillin in the patient who has received amoxicillin

previously. If not infected with *H. pylori*, review NSAID use and smoking history as appropriate. If esophagitis is seen, refer to the GERD Algorithm (#22).

Specific referral to gastroenterology may need to be considered for refractory cases.

Also refer to Annotation #6, "*H. pylori* Testing, Eradication/Case Management."

Evidence supporting this recommendation is of class: C

18. **Continue Treatment for 8 Weeks Total Course and Then Stop**

Key Points:

- Patients with dyspepsia should not receive therapy indefinitely.

Data on healing rates in both gastric and duodenal ulcers suggest that treatment with antiulcer agents should be continued to complete a course of eight weeks. The most effective agent for the majority of patients is PPI. Patients who continue NSAIDs during treatment for peptic ulcers, particularly gastric ulcers, should have the duration of PPI treatment extended to twelve weeks total.

See original guideline document for more discussion related to treatment of duodenal ulcer, gastric ulcer healing, and NSAID use.

Evidence supporting this recommendation is of classes: A, R

19. **Functional Dyspepsia**

Key Points:

- When no structural or biochemical abnormalities are identified to explain symptoms, patients may be given a diagnosis of functional or non-ulcer dyspepsia.

Additional testing may be necessary, but overtesting, overtreatment, and over-referral should be avoided. Short-term empiric trials could be considered.

Patients presenting with dyspepsia will frequently have no identifiable abnormalities on endoscopy. When no structural or biochemical abnormalities are identified to explain their symptoms, these patients may be given a diagnosis of functional or non-ulcer dyspepsia. Such patients require reassurance, and further diagnostic testing should be kept to a minimum. No medical treatment is clearly of proven benefit. At present, no firm recommendations can be made regarding the management of non-ulcer dyspepsia. Further care for functional dyspepsia should be done on a case by case basis. Eradication of *H. pylori* (if not already done), treatment with a PPI

(if not already done), prokinetic or low-dose tricyclic antidepressant, and exploration of the contribution of psychologic distress may prove beneficial. Elimination of certain foods (e.g., caffeine, alcohol, fat, etc.) or medications (e.g., NSAIDs) may help.

Specific referral to gastroenterology may need to be considered for refractory cases.

Evidence supporting this recommendation is of classes: A, R

Gastroesophageal Reflux Disease (GERD) Algorithm Annotations

22. **Symptoms of GERD**

Key Points:

- The goal is to minimize the number of patients with ulcer referred to the GERD algorithm.

GERD is the probable diagnosis if the patient has heartburn (retrosternal pain) or acid regurgitation (a sour or bitter taste in mouth) as the dominant symptom. These symptoms are sought because their presence is associated with a probability of 89% and 95%, respectively, of GERD based on studies using esophageal pH monitoring as the reference standard. The goal is to minimize the number of patients with ulcer referred to the GERD algorithm.

Atypical manifestations of GERD such as laryngopharyngeal reflux (LPR), odynophagia, water brash, globus sensation, laryngitis, chronic cough, asthma, and chest pain can also be the presenting symptoms for multiple other medical diagnoses. As previously mentioned, the role of GERD in several of these entities is uncertain and controversial. Therefore, these symptoms fall out of the scope of this guideline.

23. **Are there Alarm Features?**

Alarm features should be sought in all patients presenting with GERD. If alarm features are present, endoscopy should be performed (suggested time frames for urgency of endoscopy have been provided in italics behind each of the alarm features listed). Alarm features is a term that is used frequently in the dyspepsia literature to describe clinical features that may suggest underlying disease that should be diagnosed and treated without the delay of an empiric therapeutic trial. Alarm features frequently cited are:

- Anemia (*7-10 days*)
- Acute onset of total dysphagia (*within 1 day*)
- Hematemesis (*within 1 day if ill*)
- Melena (*within 1 day if ill*)
- Persistent vomiting (*7-10 days*)
- Weight loss greater than 5% (involuntary) (*7-10 days*)

For further discussions, please refer to "The Significance of Complicated Dyspepsia" section in Annotation #3 in the original guideline document.

25. **Initial Management (8 Weeks)**

Key Points:

- Patients with GERD may be treated without initial endoscopy.

Initial treatment of GERD should consist of an eight-week trial of PPI therapy, more long-term behavioral modifications, and possibly endoscopy, designed to help reduce reflux both structurally and promoting proper function of the lower esophageal sphincter (LES), and also reducing acidity of gastric juices.

Please refer to the original guideline document for generic names, trade names and dosing suggestions of proton pump inhibitors (PPI).

1. Dietary changes
    A. Avoid caffeine, chocolate, fats, alcohol, caffeinated and decaffeinated tea and coffee, caffeinated soft drinks, citrus juices, peppermint, and spearmint.
    B. Weight loss if indicated.
    C. Avoid large meals that may increase intra-abdominal pressure.

2. Avoid lying down after eating for 2 to 3 hours.
3. Elevate the head of the bed by 6 to 8 inches.
4. Avoid use of tobacco, with promotion of tobacco and nicotine cessation. Also consider changing medications that can lower the LES pressure (i.e., Theophylline, calcium channel blockers, and barbiturates).
5. Use of antacids on an as needed basis as well as the use of over-the-counter PPI may be of benefit.

These modifications may also take longer than eight weeks to implement for the best effect (i.e., weight loss and tobacco and alcohol abuse). These factors should be rediscussed with the patient in each subsequent phase of treatment for GERD.

For patients age 50 and more or who have had symptoms for 10 years or more, consider endoscopy prior to treatments to evaluate for Barrett's esophagus.

Following up at 8 weeks to see if there has been some improvement in symptoms may be done. If there is no improvement, the patient should be referred for endoscopy.

If these modifications have already been tried by the patient and have been successful, then advancement to maintenance therapy would be appropriate.

Evidence supporting this recommendation is of class: R

27. **Endoscopy**

Key Points:

- Patients who don't respond to therapy need endoscopic evaluation.

Flexible esophagogastroduodenoscopy should be used for the initial evaluation of esophageal symptoms in patients suspected of having GERD with refractory heartburn, odynophagia, or extra-esophageal symptoms. Endoscopy permits direct inspection and biopsy of the esophageal lining, aiding detection of grade 1 or grade 2 esophagitis--changes not apparent on x-rays. Endoscopy also permits detection and biopsy of Barrett's esophagus and eosinophilic esophagitis.

Evidence supporting this recommendation is of classes: C, D, X

28. **Positive?**

Patients with erosions, ulcerations, strictures or intestinal metaplasia (Barrett's esophagus) are considered to have a positive endoscopy. Patients who have either a normal esophageal examination or only distal esophageal erythema are considered to have a negative endoscopy.

Esophagitis as seen at endoscopy is thought to be highly specific for the diagnosis of GERD. Although infectious, caustic and pill-induced esophagitis occurs, the vast majority of patients with linear erosions in their distal esophagus will have gastroesophageal reflux. Esophagitis is graded on a continuum from mild to severe. Mild, non-erosive esophagitis is common at endoscopy and may not correlate well with the patient's symptoms. For this reason, esophagitis of moderate severity is recommended before making a positive diagnosis of GERD.

Evidence supporting this recommendation is of class: C

29. **Case Management for Negative Endoscopy**

Key Points:

- The diagnosis of GERD can be challenging in patients who don't respond to therapy and have negative endoscopies.

Diagnosing GERD can be difficult in patients with atypical symptoms, noncardiac chest pain, or normal endoscopy. Many diagnostic tests to find pathological reflux have been developed. Few of them have withstood rigorous scientific testing and lack relevance to clinical management.

Manometry defines lower esophageal sphincter pressure accurately but does not identify the presence of significant reflux. The water siphon test (sipping water in supine position during a barium esophagram) has a sensitivity of only 60% and a false positive rate of 30%.

Spot esophageal pH measurements are only 58% sensitive in esophagitis patients and measure esophageal pH only briefly. The standard esophagram also performs poorly in esophagitis patients (sensitivities range from 5% in grade 1 and 18% in grade 2 to 60% in grade 4). Gastroesophageal reflux scintiscanning has been reported to be 90% sensitive by one medical center; however, this result has not been readily reproducible, remains quite expensive, and has not been widely accepted as clinically useful.

Therefore, 24-hour pH monitoring has been adopted as the diagnostic standard. 24-hour pH monitoring measures longer periods, captures transient pH changes not associated with symptoms, and can be coded into a scientific scoring system yielding acceptable sensitivities. These strengths make it the most useful test in patients with surreptitious disease and normal endoscopy. However, pH monitoring does not provide evidence of causality.

PPIs are capable of marked acid suppression and may allow a simultaneous empiric, therapeutic, and diagnostic trial.

Alternatively, a trial and practical experience suggest short-term administration of high-dose proton pump inhibitors (PPIs) can reduce symptoms and offer a reasonably accurate diagnostic discrimination in selected groups of patients with suspected GERD. All patients with complaints of heartburn do not necessarily have GERD. Patients who don't respond to therapy, and have negative pH studies should be considered to have functional heartburn. These patients should be individually managed, as are patients with other functional gastrointestinal disorders (i.e., irritable bowel syndrome, non-ulcer dyspepsia.)

Therefore, the administration of high-dose PPI appears useful as a diagnostic and therapeutic trial in selected groups of patients with non-cardiac chest pain, atypical symptoms, or a normal endoscopy.

Specific referral to gastroenterology may need to be considered for refractory cases.

Evidence supporting this recommendation is of class: C

30. **Case Management for Refractory Reflux**

Key Points:

- Some patients with GERD need higher doses of medication or consideration of surgery.

Patients with erosive esophagitis or worse should be treated with proton pump inhibitors (PPI) in a double therapeutic dose. If Esomeprazole (Nexium®) has not been used at this point, it would be reasonable to try a therapeutic trial. Patients intolerant of PPIs may receive a quadruple therapeutic dose of H_2RA. Failure to respond should prompt doubling the dose of the antisecretory medication and referral to gastroenterology. Duration of treatment should be indefinite within a single trial of step-down.

Patients requiring long-term maintenance therapy, or those who are incompletely controlled on maintenance therapy with a single trial of step-down, may wish a surgical opinion regarding fundoplication or bariatric surgery (body mass index [BMI] greater than 35), or GI opinion regarding endoscopic approaches.

Essential elements in case management of esophagitis that is erosive or worse (moderate or worse) include selection of cost-effective treatment, the need for maintenance treatment, consideration of surgical treatment, and the need for referral to gastroenterology.

Relief of symptoms and healing of esophagitis are dependent on the degree and duration of acid suppression. Routine therapeutic doses of PPI are only fair at best in treating this minority subset of patients at the more severe end of the disease spectrum. For acute healing, a two-month course of standard dose PPIs (lansoprazole, omeprazole, rabeprazole, pantoprazole, esomeprazole) is recommended. Cost analyses are limited to decision models but suggest that PPIs are cost-effective compared to branded H_2RA. When compared to generic cimetidine, PPIs are of equivalent cost-effectiveness; consequently, the clinically superior treatment (i.e., PPIs) should be favored.

The challenge of treating erosive or more severe esophagitis is the very high rate of relapse with discontinuation of treatment or with step down treatment. The relapse rate is greater than 90% at 6 months. Because of that, ongoing support for lifestyle modifications is essential. However, present evidence from clinical trials would suggest that the treatment providing symptom relief and healing should be continued long-term. The most cost-effective approach is established for those with peptic ulcers. Long-term PPIs are superior. For those with less severe esophagitis, decision models are divided on the preferred approach: continuation of PPIs, or PPIs only after failure of one trial of step down therapy.

Decisions regarding referral to gastroenterology and surgery should be at the discretion of patient and physician. Long-term use of PPIs is established as safe. For those on a usual dose of PPIs with good symptom control, this is acceptable long-term treatment. For those not controlled or requiring a double dose of PPIs, referral to gastroenterology or surgery should be considered. Decision modeling of laparoscopic fundoplication versus long-term PPIs does not establish a preferred cost-effective option. Controlled studies of this question are underway.

Specific referral to gastroenterology may need to be considered for refractory cases.

Evidence supporting this recommendation is of classes: A, M, R

31. **Encourage Single Trial Step-Down Therapy**

Key Points:

- All patients with GERD should have one attempt at discontinuation therapy.

Patients with uncomplicated reflux may benefit from step-down therapy. Step-down therapy gradually reduces the intensity of treatment as tolerated to maintain the patient in remission. Lifestyle modifications should be continued indefinitely. Patients whose initial symptoms were controlled by lifestyle measures initially may require only occasional PPIs.

The availability of OTC PPI and associated cost reduction permits the use of this therapy for initial management of GERD. The use of initial PPI has been shown to reduce heartburn severity and duration compared to the use of H_2RA. This was the case when H_2RA was used alone, used in a program that permitted use of PPI either initially, followed by PPI ("step down"), or after a failed trial of H_2RA ("step up").

Evidence supporting this recommendation is of classes: A, D, R

34. **Return to Chronic PPI Therapy**

Key Points:

- Most patients with GERD need therapy long term.

Most patients with typical reflux symptoms will respond to acid suppressive therapy. This guideline encourages trying to reduce the therapy over time but many patients will stay on such therapy for months if not years. As long as these patients are not symptomatic, they do not require an endoscopy.

Some groups have suggested, however, that patients with reflux should have an endoscopy to screen for Barrett's esophagus (BE). BE is a change in the lining of the esophagus from the normal squamous mucosa to a metaplastic intestinal columnar mucosa. Patients with BE are at increased risk of adenocarcinoma of the esophagus and thus patients with BE are placed into endoscopic surveillance programs.

The American College of Gastroenterology recommends: "Patients with chronic GERD symptoms are those most likely to have Barrett's esophagus and should undergo endoscopy."

At present there are no data to demonstrate the cost-effectiveness of such a strategy. Patients with longer duration of symptoms (greater than 10 years) are more likely to have BE. White men are at increased risk.

Selecting patients on the basis of risk would improve the cost-effectiveness but has not been incorporated into guidelines. Given the absence of clear evidence of benefit, screening for Barrett's esophagus in patients with GERD cannot be advocated in all patients.

Patients requiring long-term maintenance therapy, or those who are incompletely controlled on maintenance therapy with a single trial of step-

down, may wish a surgical opinion regarding fundoplication or bariatric surgery (BMI greater than 35), or a gastroenterology opinion regarding endoscopic approaches.

Evidence supporting this recommendation is of class: R

Definitions:

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

Classes of Research Reports:

A. Primary Reports of New Data Collection:

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Nonrandomized trial with concurrent or historical controls

- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

CLINICAL ALGORITHM(S)

Detailed and annotated clinical algorithms are provided for:

- Dyspepsia
- Gastroesophageal Reflux Disease (GERD)

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is classified for selected recommendations (see "Major Recommendations").

In addition, key conclusions contained in the Work Group's algorithm are supported by a grading worksheet that summarizes the important studies pertaining to the conclusion. The type and quality of the evidence supporting these key recommendations (i.e., choice among alternative therapeutic approaches) is graded for each study.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate evaluation and initial management of epigastric discomfort, including management of patients with dyspepsia and gastroesophageal reflux disease (GERD)

POTENTIAL HARMS

The proton pump inhibitors (PPIs) are metabolized via hepatic cytochrome P450 enzymes, with CYP2C19 having the dominant role. However, the dominance of this route varies significantly among the PPIs. The specific P450 enzymes involved in PPI metabolism and the potential for interactions among these agents shows variation. Omeprazole is metabolized largely via CYP2C19, and the potential for interactions thus appears to be the greatest among the PPIs. If this metabolic pathway becomes saturated, there is the possibility for interactions with many drugs, including warfarin, diazepam, and phenytoin. While rabeprazole is also metabolized by this isoenzyme, it apparently possesses significant affinity for CYP3A4; very few interactions have been documented with rabeprazole. Lansoprazole is metabolized principally via CYP3A4, and interactions with theophylline have been reported. As the metabolism of pantoprazole primarily involves CYP2C19 O-demethylation, significant CYP3A4 and CYP1A induction is not seen. This agent has the lowest potential for P450 metabolism and drug interactions.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These clinical guidelines are designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and are not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.
- This clinical guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients are urged to consult a health care professional regarding their own situation and any specific medical questions they may have.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Once a guideline is approved for release, a member group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form an action group.

In the action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment and tobacco cessation.

The following detailed measurement strategies are presented to help close the gap between clinical practice and the guideline recommendations.

Priority Aims and Suggested Measures for Health Care Systems

1. To increase the use of recommended methods for evaluating dyspepsia.

   Possible measures of accomplishing this aim:

   a. Percentage of patients evaluated for dyspepsia with discussion regarding appropriate *Helicobacter pylori* testing.
   b. Percentage of patients evaluated for dyspepsia without standard single-phase contrast studies.
   c. Percent of patients evaluated for dyspepsia with endoscopy prior to receiving a therapeutic trial who do not have an alarm feature present.
2. To increase appropriate pharmaceutical treatment of patients with dyspepsia.

   Possible measures of accomplishing this aim:

   a. Percentage of patients with dyspepsia positive for *H. pylori* who receive antibiotic therapy.
   b. Percentage of patients with dyspepsia treated with antibiotics for positive *H. pylori* who receive effective therapy.
   c. Percentage of patients with dyspepsia treated with a proton pump inhibitor (PPI) without previous endoscopic examination.
3. To decrease complications associated with peptic ulcer disease.

   Possible measure of accomplishing this aim:

   a. Number or rate of hospital admissions for ulcer hemorrhage.
4. To improve functional outcomes and satisfaction of patients with dyspepsia.

   Possible measures of accomplishing this aim:

   a. Percentage of patients with dyspepsia with improved symptoms following treatment as measured by a dyspepsia-specific health status instrument.
   b. Percentage of patients with dyspepsia who report that they are satisfied or very satisfied following treatment for dyspepsia.
5. Increase the use of initial treatment recommendations for evaluating gastroesophageal reflux disease (GERD).

Possible measures for accomplishing this aim:

a. Percentage of patients with GERD following behavioral modification recommendations.
b. Percentage of patients with GERD treated with PPI for an 8-week period.
c. Percentage of patients with GERD reporting relief of symptoms after 8-week trial of PPI.
d. Percentage of patients with GERD and control of symptoms with a PPI who have had a trial of step down therapy.
e. Percentage of patients with GERD who are not tested for *H. pylori*.

6. To increase appropriate treatment for patients who have ongoing symptoms after initial treatment recommendations.

   Possible measures for accomplishing this aim:

   a. Percentage of patients with continued symptoms of GERD after an 8-week trial of PPI having an endoscopy.
   b. Percentage of patients age 50 (and over) who have GERD or a history of GERD for 10 years or more who have been evaluated with endoscopy.
   c. Percentage of patients with ongoing symptoms of GERD (see annotation #1) and a body mass index [BMI] greater than 35 referred for surgical opinion regarding fundoplication or bariatric surgery.

At this point in development for this guideline, there are no specifications written for the possible measures listed above. The Institute for Clinical Systems Improvement (ICSI) will seek input from medical groups on what measures are of most use as they implement the guideline. In a future revision of the guideline, measurement specifications may be included.

IMPLEMENTATION TOOLS

Clinical Algorithm
Pocket Guide/Reference Cards

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

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Initial management of dyspepsia and GERD. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2006 Jul. 53 p. [100 references]

ADAPTATION

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

DATE RELEASED

1998 Oct (revised 2006 Jul)

GUIDELINE DEVELOPER(S)

Institute for Clinical Systems Improvement - Private Nonprofit Organization

GUIDELINE DEVELOPER COMMENT

Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Community Medical Centers, Allina Medical Clinic, Altru Health System, Aspen Medical Group, Avera Health, CentraCare, Columbia Park Medical Group, Community-University Health Care Center, Dakota Clinic, ENT Specialty Care, Fairview Health Services, Family HealthServices Minnesota, Family Practice Medical Center, Gateway Family Health Clinic, Gillette Children's Specialty Healthcare, Grand Itasca Clinic and Hospital, HealthEast Care System, HealthPartners Central Minnesota Clinics, HealthPartners Medical Group and Clinics, Hutchinson Area Health Care, Hutchinson Medical Center, Lakeview Clinic, Mayo Clinic, Mercy Hospital and Health Care Center, MeritCare, Mille Lacs Health System, Minnesota Gastroenterology, Montevideo Clinic, North Clinic, North Memorial Care System, North Suburban Family Physicians, Northwest Family Physicians, Olmsted Medical Center, Park Nicollet Health Services, Pilot City Health Center, Quello Clinic, Ridgeview Medical Center, River Falls Medical Clinic, Saint Mary's/Duluth Clinic Health System, St. Paul Heart Clinic, Sioux Valley Hospitals and Health System, Southside Community Health Services, Stillwater Medical Group, SuperiorHealth Medical Group, University of Minnesota Physicians, Winona Clinic, Ltd., Winona Health

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GUIDELINE COMMITTEE

Committee on Evidence-Based Practice

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

In the interest of full disclosure, ICSI has adopted a policy of revealing relationships work group members have with companies that sell products or services that are relevant to this guideline topic. The reader should not assume that these financial interests will have an adverse impact on the content of the guideline, but they are noted here to fully inform readers. Readers of the guideline may assume that only work group members listed below have potential conflicts of interest to disclose.

G. Richard R. Locke, MD is a consultant for Boehringer Ingelheim, Glaxo SmithKline, Solvay, and Novartis and receives research grant support from AstraZeneca, Forest Laboratories, Glaxo SmithKline, TAP, Boehringer Ingelheim, Novartis, and Janssen Pharmaceutica.

Nicholas J. Talley, MD is a consultant for Altana, AstraZeneca, Axcan, Chugai, BBMed, Giaconda, Glaxo-SmithKline, Kosan, KV Pharmaceuticals, Medscape, ProEd Communications, Renovis Inc., Solvay, Strategic Consultants International, Takeda Pharmaceuticals Inc., TAP, Therapeutic Gastrointestinal Group, Theravance, and Yamanouchi. He also receives research grant support from Merck, Novartis, TAP, Axcan, Boehringer Ingelheim, and Forest.

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ICSI's conflict of interest policy and procedures are available for review on ICSI's website at www.icsi.org.

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This is the current release of the guideline.

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GUIDELINE AVAILABILITY

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Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Initial management of dyspepsia and GERD. Executive summary. Bloomington (MN): Institute for Clinical Systems Improvement, 2006 Jul. 1 p. Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site.
- ICSI pocket guidelines. April 2006 edition. Bloomington (MN): Institute for Clinical Systems Improvement, 2006. 298 p.

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PATIENT RESOURCES

None available

NGC STATUS

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