# Complete Summary

## GUIDELINE TITLE

Gastroesophageal reflux disease (GERD).

## BIBLIOGRAPHIC SOURCE(S)

University of Michigan Health System. Gastroesophageal reflux disease (GERD). Ann Arbor (MI): University of Michigan Health System; 2007 Jan. 10 p. [9 references]

## GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: University of Michigan Health System. Management of gastroesophageal reflux disease (GERD). Ann Arbor (MI): University of Michigan Health System; 2002 Mar. 9 p.

## COMPLETE SUMMARY CONTENT



## SCOPE

### DISEASE/CONDITION(S)

Gastroesophageal reflux disease (GERD)

### GUIDELINE CATEGORY

Diagnosis
Management
Treatment

### CLINICAL SPECIALTY

Family Practice
Gastroenterology
Internal Medicine

## INTENDED USERS

Advanced Practice Nurses
Nurses
Pharmacists
Physician Assistants
Physicians

## GUIDELINE OBJECTIVE(S)

To implement a cost-effective and evidence-based strategy for the diagnosis and treatment of gastroesophageal reflux disease (GERD)

## TARGET POPULATION

Adults with suspected or confirmed gastroesophageal reflux disease (GERD)

## INTERVENTIONS AND PRACTICES CONSIDERED

### Diagnosis

1. History
2. Testing
    - Esophageal pH monitoring
    - Endoscopy
    - Barium radiology (considered but not recommended)
3. Therapeutic trials of acid suppression therapy

### Treatment

1. Lifestyle modifications
2. Pharmacologic treatment
    - Histamine type-2 receptor antagonists (H2RAs)
    - Proton pump inhibitors (PPIs)
    - Supplemental acid-neutralizing agents
    - Over-the-counter (OTC) remedies (antacids, combined antacid/alginic acids, H2RAs)
3. Anti-reflux surgery
4. Alternative endoscopic treatments
    - Radiofrequency heating of the gastroesophageal (GE) junction
    - Endoscopic gastroplasty

### Maintenance Regimens

1. *Step-up therapy*. Start with less potent agents and move up for treatment response.

2. *Step-down therapy*. Start with potent acid suppression initially and decrease dose or agents or treatment response.
3. *On-demand therapy*. Treatment can be initiated with standard dosage of either a PPI daily or an H2RA twice daily on demand (patient directed therapy). Drug selection depends on clinical presentation, cost-effectiveneess, and end point of appropriate symptom relief.

**Follow Up**

1. Referral to specialists
2. Further diagnostic testing for those non-responsive to acid suppression therapy or at risk for complications
    - Esophagogastroduodenoscopy (EGD)
    - Ambulatory pH monitoring of intraesophageal acidity
    - Esophageal dilation for stricture formation

### MAJOR OUTCOMES CONSIDERED

- Sensitivity and specificity of diagnostic tests
- Rate of symptomatic relief
- Esophagitis healing rates
- Medication and treatment side effects

## METHODOLOGY

### METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The literature search began with the results of the literature search performed through September 2000 for the previous version of this guideline. The results of two more recent literature searches were reviewed:

> American College of Gastroenterology: Updated Guidelines for the diagnosis and treatment of gastroesophageal reflux disease (2005), literature search through early 2004.
>
> VA/DOD Clinical Practice Guideline for the Management of Adults with Gastroesophageal Reflux Disease in Primary Care Practice (2003), literature search through May 2002.

A search of more recent literature was conducted prospectively on Medline from January 2004 through May 2006 using the major keywords of: gastroesophageal reflux disease (or GERD, NERD [non-erosive reflux disease], NEED [non-erosive esophageal disease]), human adults, English language, clinical trials, and guidelines. Terms used for specific topic searches within the major key words included: symptoms (atypical symptoms, heartburn, retrosternal burning sensation precipitated by meals or a recumbent position, hoarseness, laryngitis,

sore throat, chronic cough, chest pain, bronchospasm/asthma, dental erosions) nocturnal (or nocturnal breakthrough, night time), endoscopy, pH recording, manometry, provocative testing (Bernstein's), video esophagography, empiric/therapeutic trial to acid suppression, lifestyle measures/treatment (avoiding fatty foods, chocolate, peppermints, ethanol-containing beverages; recumbency for 3 hours after a meal; elevating head of bed; weight loss), antacids, alginic acid (gaviscon), carafate, prokinetic agents (cisapride, metoclopramide, bethanechol, dromperidone), H2 receptor antagonists (nizatidine, ranitidine, famotidine, cimetidine), proton pump inhibitors (omeprazole, lansoprazole, rabeprazole, pantoprazole, esomeprazole), fundoplication (open vs. laparoscopy; endoscopic antireflux procedures), Barrett's esophagus (screening, surveillance). Detailed search terms and strategy available upon request.

The search was conducted in components each keyed to a specific causal link in a formal problem structure (available upon request). The search was supplemented with very recent information available to expert members of the panel, including abstracts from recent meetings and results of clinical trials. Negative trials were specifically sought. The search was a single cycle.

## 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

### Levels of Evidence

A. Randomized controlled trials
B. Controlled trials, no randomization
C. Observational trials
D. Opinion of expert panel

## METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

## DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Conclusions were based on prospective randomized clinical trials (RCTs) if available, to the exclusion of other data. If RCTs were not available, observational studies were admitted to consideration. If no such data were available for a given link in the problem formulation, expert opinion was used to estimate effect size.

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

### DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

### RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

### COST ANALYSIS

An in-depth examination of various cost-effective approaches to gastroesophageal reflux disease (GERD) was reviewed.

An economic appraisal reviewing different treatment modalities and their cost-effectiveness was reviewed. Proton pump inhibitors were considered more cost effective than H2 receptor antagonists in those with documented erosive esophagitis.

### METHOD OF GUIDELINE VALIDATION

Peer Review

### DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

University of Michigan Health System (UMHS) guidelines are reviewed by clinical conferences of physicians in departments to which the content is most relevant and by leadership in those departments/divisions. This guideline concerning GERD was reviewed by members of the following departments/divisions: Gastroenterology, General Medicine; Family Medicine.

Guidelines are approved by the Executive Committee of Clinical Affairs (ECCA).

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

*Note from the National Guideline Clearinghouse (NGC)*: The following key points summarize the content of the guideline. Refer to the full text for additional information, including detailed information on dosing, possible side effects, and cost of medications; esophagitis classification scale; other interventions; considerations for special patient populations (older adults; patients with atypical manifestations of gastroesophageal reflux, Barrett's esophagus, or *Helicobacter. pylori* positivity).

Definitions for the levels of evidence (A, B, C, D) are provided at the end of the Major Recommendations field.

**Diagnosis**

- *History*. A well-taken history is essential in establishing a diagnosis of gastroesophageal reflux disease (GERD). If the classic symptoms of heartburn and acid regurgitation clearly dominate a patient's history, they can help establish the diagnosis of GERD with sufficiently high specificity, although sensitivity of clinical history remains low compared to 24-hour pH monitoring. The presence of atypical symptoms (see table below), although common, cannot sufficiently support the clinical diagnosis of GERD. *[B]*

  **Table. Atypical Signs of Gastrointestinal Reflux Disease GERD**

| |
|---|
| Chronic cough |
| Asthma |
| Recurrent sore throat |
| Recurrent laryngitis |
| Dental enamel loss |
| Subglottic stenosis |
| Globus sensation |
| Chest pain |
| Onset of symptoms at age > 50 |

- *Testing*. No gold standard exists for the diagnosis of GERD *[A]*. Although pH probe is accepted as the standard with a sensitivity of 85% and specificity of 95%, false positives and false negatives still exist *[B]*. Endoscopy lacks sensitivity in determining pathologic reflux. Barium radiology has limited usefulness in the diagnosis of GERD and is not recommended *[B]*.
- *Therapeutic trial*. An empiric trial of acid suppression therapy can identify patients with GERD who do not have alarm symptoms *[A]* and may be helpful in the evaluation of those with atypical manifestations of GERD, specifically, non-cardiac chest pain (NCCP) *[B]*.

**Treatment**

- *Lifestyle modifications*. Lifestyle modifications should be recommended throughout the treatment of GERD, but there is little evidence-based data to support their efficacy *[D]*.
- *Pharmacologic treatment*. H2-receptor antagonists (H2RAs), proton pump inhibitors (PPIs), and prokinetics have proven efficacy in the treatment of GERD *[A]*. Past prokinetics have been as effective as H2RAs but are currently unavailable *[A]*. Carafate and antacids are ineffective *[A]*, but may be used as supplemental acid-neutralizing agents for certain patients with GERD *[D]*.
    - Non-erosive reflux disease (NERD). Step-up (H2RAs followed by a PPI if no improvement) and step-down (PPI followed by the lowest dose of

acid suppression) therapy are equally effective for both acute treatment and maintenance *[C]*. Costs for step-down treatment are mainly medications, while step-up treatment requires more frequent endoscopy. On demand (patient-directed) therapy is the most cost-effective strategy.
    - Documented erosive esophagitis. Initial PPI therapy is the treatment of choice for acute and maintenance therapy for patients with documented erosive esophagitis *[A]*.
    - PPI's should be taken 30 to 60 minutes prior to a meal to optimize effectiveness *[B]*.
- *Surgery*. Antireflux surgery is an alternative modality in the treatment of GERD in patients who have documented chronic reflux with recalcitrant symptoms *[A]*. Surgery has a significant complication rate (10-20%). Resumption of pre-operative medication treatment (>50%) is common and will likely increase over time.
- *Other endoscopic modalities*. Some alternative endoscopic modalities are less invasive and have fewer complications, but are also likely to have lower response rates than antireflux surgery *[C]*, and have not been shown to reduce acid exposure.

**Follow Up**

- *Symptoms unchanged*. If symptoms remain unchanged in a patient with a prior normal endoscopy, repeating endoscopy has no benefit and is not recommended *[C]*.
- *Warning signs*. Patients with warning signs and symptoms suggesting complications from GERD (see table below) should be referred to a GERD specialist.

**Table. Warning Signs Suggesting Complicated GERD**

| |
|---|
| Dysphagia |
| Odynophagia |
| Gastrointestinal bleeding |
| Iron deficiency anemia |
| Weight loss |
| Early satiety |
| Vomiting |

- *Risk for complications*. Further diagnostic testing (e.g., esophagogastroduodenoscopy [EGD], pH monitoring) should be considered in patients who do not respond to acid suppression therapy *[C]* and in patients with a chronic history of GERD who are at risk for complications (e.g., Barrett's esophagus, adenocarcinoma, stricture). Chronic reflux has been suspected to play a major role in the development of Barrett's esophagus, yet it is unknown if outcomes can be improved through surveillance and medical

treatment *[D]*. Costs of surveillance for Barrett's Esophagus without dysplasia are likely to be prohibitive *[B]*. Anti-reflux therapy has been shown to reduce the need for recurrent dilation from esophageal stricture formation *[A]*.

**Definitions**:

**Levels of Evidence**

Levels of evidence reflect the best available literature in support of an intervention or test.

A. Randomized controlled trials
B. Controlled trials, no randomization
C. Observational trials
D. Opinion of expert panel

### CLINICAL ALGORITHM(S)

An algorithm for diagnosis and treatment of gastroesophageal reflux disease (GERD) is provided in the original guideline document.

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see Major Recommendations).

Conclusions were based on prospective randomized clinical trials if available, to the exclusion of other data; if randomized controlled trials were not available, observational studies were admitted to consideration. If no such data were available for a given link in the problem formulation, expert opinion was used to estimate effect size.

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

Accurate diagnosis and appropriate, cost-effective treatment of gastroesophageal reflux disease (GERD)

### POTENTIAL HARMS

- H2 receptor antagonists (H2RAs) have been associated with rare cytopenias, gynecomastia, liver function test abnormalities, and hypersensitivity reactions.
- Proton pump inhibitors (PPIs) have been associated with rare vitamin B12 deficiencies, community-acquired pneumonia, Clostridium difficile colitis, and hip fracture

- Post antireflux surgical complications are common, but typically short term and manageable in most instances. Short term solid food dysphagia occurs in 10% of patients (2 to 3% have permanent symptoms) and gas bloating occurs in 7-10% of patients. Diarrhea, nausea and early satiety occur more rarely. While some complication occurs in up to 20% of patients, major complications occur in only 3 to 4% of patients.

## QUALIFYING STATEMENTS

### QUALIFYING STATEMENTS

These guidelines should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific clinical procedure or treatment must be made by the physician in light of the circumstances presented by the patient.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

### IMPLEMENTATION TOOLS

Clinical Algorithm
Patient Resources
Staff Training/Competency Material

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
Patient-centeredness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

University of Michigan Health System. Gastroesophageal reflux disease (GERD). Ann Arbor (MI): University of Michigan Health System; 2007 Jan. 10 p. [9 references]

## ADAPTATION

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

## DATE RELEASED

2002 Mar (revised 2007 Jan)

## GUIDELINE DEVELOPER(S)

University of Michigan Health System - Academic Institution

## SOURCE(S) OF FUNDING

University of Michigan Health System

## GUIDELINE COMMITTEE

Gastroesophageal Reflux Disease (GERD) Guideline Team

## COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

*Team Leader*: Joel J Heidelbaugh, MD, Family Medicine

*Team Members*: Arvin S Gill, MD, Internal Medicine; R Van Harrison, PhD, Medical Education; Timothy T Nostrant, MD, Gastroenterology

*Guidelines Oversight Team*: Connie J Standiford, MD; William E Chavey, MD; R Van Harrison, PhD

## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The University of Michigan Health System endorses the Guidelines of the Association of American Medical Colleges and the Standards of the Accreditation Council for Continuing Medical Education that the individuals who present educational activities disclose significant relationships with commercial companies whose products or services are discussed. Disclosure of a relationship is not intended to suggest bias in the information presented, but is made to provide readers with information that might be of potential importance to their evaluation of the information.

**Team Members; Relationship; Company**:

Joel J. Heidelbaugh, MD (None)

Arvin Gill, MD (None)

R. Van Harrison, PhD (None)

Timothy T. Nostrant, MD; Consultant; Astra-Zeneca, Janssen (J & J), Sartoris, Tapp (Takeda), Wyeth

## GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: University of Michigan Health System. Management of gastroesophageal reflux disease (GERD). Ann Arbor (MI): University of Michigan Health System; 2002 Mar. 9 p.

## GUIDELINE AVAILABILITY

Electronic copies: Available for download in Portable Document Format (PDF) from the University of Michigan Health System Web site.

## AVAILABILITY OF COMPANION DOCUMENTS

Continuing Medical Education (CME) information is available from the University of Michigan Health System Web site.

## PATIENT RESOURCES

The following are available:

- Gastroesophageal reflux disease (GERD). University of Michigan Health System; 2006 Dec. Various p. Available from the University of Michigan Health System Web site.
- Gastroesophageal reflux disease (GERD) - patient instructions. University of Michigan Health System; 2006 Dec. Various p. Available from the University of Michigan Health System Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

## NGC STATUS

This NGC summary was completed by ECRI on January 7, 2003. The information was verified by the guideline developer on February 4, 2003. This NGC summary was updated by ECRI Institute on April 23, 2007. The updated information was verified by the guideline developer on April 25, 2007.

## COPYRIGHT STATEMENT

This NGC summary is based on the original guideline, which is copyrighted by the University of Michigan Health System (UMHS).

## DISCLAIMER

### NGC DISCLAIMER

The National Guideline Clearinghouse™ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at http://www.guideline.gov/about/inclusion.aspx .

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.



Date Modified: 10/13/2008