January 1, 2004

Dear Doctor:

We are pleased to present HMSA's Collection of Clinical Practice Guidelines for 2004. The guidelines included in this publication address some of the most prevalent clinical conditions facing health care professionals today. This year, we've added three new guidelines - Headache, Osteoporosis for Post-menopausal Women, and Chronic Obstructive Pulmonary Disease. We have also made revisions to many of the existing guidelines.

These guidelines were selected and approved in collaboration with local practicing physician reviewers to reflect current, evidence-based practice. The guidelines serve as an educational reference and do not supersede the clinical judgment of the treating physician with respect to appropriate and necessary care for a particular patient. The clinical references from which these guidelines were taken are listed with each guideline along with website locations.

We hope that you will find these guidelines informative and easy to use. These guidelines will be reviewed and updated annually. If you have any questions or suggestions for improvement, please feel free to call Dr. Ron Fujimoto at 948-5931.

Sincerely,

Richard Chung, MD
Vice President/Medical Director
Care Management

John Berthiaume, MD
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Medical Director
Care Management
Acknowledgements

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- Elizabeth Tam, MD
- Dennis Wachi, MD
- Allan Wang, MD
- Ira Zunin, MD

Should you have any questions regarding any of the guidelines, please contact Dr. Ron Fujimoto, Medical Director, Care Management at 948-5931.
Feedback Form – Clinical Practice Guidelines 2004

We value your opinion! Please tell us what you think of HMSA’s Clinical Practice Guidelines for 2004 in the space below and fax this sheet at the number located at the bottom of this page.

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Additional Resource Material

HMSA has resource pamphlets and materials to supplement the HMSA Clinical Practice Guidelines. Additional material is available upon request for the following guidelines:

☐ Asthma ☐ Chronic Obstructive Pulmonary Disease

Please check the box(es) of the resource materials you wish to receive and fill in your mailing address information below.

Name: ____________________________
Address: __________________________

City, ZIP: _________________________

Please fax this feedback/request form to 948-6043
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Asthma
Comprehensive Management

Introduction

Asthma is a chronic inflammatory disease of the airway. In the United States, asthma affects between 14 and 15 million people. It is the most common chronic disease of childhood, affecting an estimated 4.8 million children (Adams and Marano 1995; Centers for Disease Control and Prevention 1995). People with asthma collectively have more than 100 million days of restricted activity and 470,000 hospitalizations annually. More than 5,000 people die of asthma annually. Asthma hospitalization rates have been highest among blacks and children, while death rates for asthma were consistently highest among blacks ages 15 to 24 (Centers for Disease Control and Prevention, 1996). These rates have increased or remained stable over the past decade. This guideline describes the appropriate use of the available therapies in the management of asthma.

Goals/Desired Outcomes

The Expert Panel Report 2: Guidelines for the Diagnosis and Management of Asthma serves as a comprehensive guide to diagnosing and managing asthma. Implementation of EPR-2 recommendations is likely to increase some costs of asthma care by increasing the number of primary care visits for asthma and the use of asthma medications, environmental control products and services, and equipment (e.g., spacer/holding chamber devices). However, asthma diagnosis and management are expected to improve, which should reduce the number of lost school and work days, hospitalizations and emergency department visits, and deaths due to asthma.

Diagnosis

Initial assessment and diagnosis of asthma

Making the correct diagnosis of asthma is extremely important. Clinical judgement is required because signs and symptoms vary widely from patient to patient as well as within each patient over time. To establish the diagnosis of asthma, the clinician must determine the following:

- Episodic symptoms of airflow obstruction are present.
- Airflow obstruction is at least partially reversible.
- Alternative diagnoses are excluded.

Periodic assessment and monitoring

To establish whether the goals of asthma therapy have been achieved, ongoing monitoring and periodic assessment are needed. The goals of asthma therapy are as follows:

- Prevent chronic and troublesome symptoms.
- Maintain (near) "normal" pulmonary function.
- Maintain normal activity levels (including exercise and other physical activity).
Asthma

Comprehensive Management

- Prevent recurrent exacerbations of asthma and minimize the need for emergency department visits or hospitalizations.
- Provide optimal pharmacotherapy with minimal or no adverse effects.
- Meet patients' and families' expectations of, and satisfaction with, asthma care.

Several types of monitoring are recommended: signs and symptoms, pulmonary function, quality of life/functional status, history of asthma exacerbations, pharmacotherapy, and patient-provider communication and patient satisfaction.

The panel recommends that patients, especially those with moderate-to-severe persistent asthma or a history of severe exacerbations, be given a written action plan based on signs and symptoms and/or peak expiratory flow. Daily peak flow monitoring is recommended for patients with moderate-to-severe persistent asthma. In addition, the panel states that any patient who develops severe exacerbations may benefit from peak flow monitoring.

Treatment

Control of factors contributing to asthma severity
Exposure of sensitive patients to inhalant allergens has been shown to increase airway inflammation, airway hyperresponsiveness, asthma symptoms, need for medication, and death. Substantially reducing exposures to inhalant allergens significantly reduces these outcomes. Environmental tobacco smoke is a major precipitant of asthma symptoms in children. Tobacco smoke increases symptoms and the need for medications, and reduces lung function in adults. Increased air pollution levels of respirable particulates, ozone, SO₂, and NO₂ have been reported to precipitate asthma symptoms and increase emergency department visits and hospitalizations for asthma. Other factors that can contribute to asthma severity include rhinitis and sinusitis, gastroesophageal reflux, certain medications, and viral respiratory infections.

Pharmacologic therapy
Expert Panel Report-2 (EPR-2) offers an extensive discussion of the pharmacologic management of patients at all levels of asthma severity. It is noted that asthma pharmacotherapy should be instituted in conjunction with environmental control measures that reduce exposure to factors known to increase the patient’s asthma symptoms. As in the 1991 report, a stepwise approach to pharmacologic therapy is recommended, with the type and amount of medication dictated by asthma severity.
Observations into the basic mechanisms of asthma have had a tremendous influence on therapy. Because inflammation is considered an early and persistent component of asthma, therapy for persistent asthma must be directed toward long-term suppression of the inflammation.

**Highlights based on National Asthma Education and Prevention Program (NAEPP) 2002 updates:**

- Inhaled corticosteroids are preferred for controlling and preventing asthma symptoms, and for improving lung function and quality of life. Inhaled steroids treat chronic inflammation of the airways, which has been confirmed as a key characteristic of asthma.
- Antibiotics should not be used to treat acute asthma attacks except when a bacterial infection due to another condition is present, such as pneumonia or sinusitis.
- A Cochrane review of 25 studies demonstrates that self-management interventions with written action plans have the greatest benefits, including reduced emergency department visits and hospitalizations and improved lung function.

**Changes based on NAEPP 2002 Updates:**

- Adding long-acting inhaled beta₂-agonists to inhaled steroids is more effective than simply increasing the dose of inhaled steroids for patients over the age of five who have moderate or severe persistent asthma.
- Large clinical trials have shown that the potential risk of a delay in growth linked to inhaled corticosteroids is temporary and possibly reversible. Other potential concerns, such as reduced bone mineral density, suppressed adrenal function, and increased incidence of cataracts are not considered significant risks for children.
- New recommendations have been included regarding the use of leukotriene modifiers as alternative therapy for treating mild persistent asthma or as combination therapy in moderate asthma.
### Stepwise Approach for Managing Infants and Young Children (5 Years of Age and Younger) With Acute or Chronic Asthma

<table>
<thead>
<tr>
<th>Classify Severity: Clinical Features Before Treatment or Adequate Control</th>
<th>Medications Required To Maintain Long-Term Control</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Symptoms/Day</strong></td>
<td><strong>Daily Medications</strong></td>
</tr>
<tr>
<td><strong>Symptoms/Night</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Step 4</strong></td>
<td><strong>Severe Persistent</strong></td>
</tr>
</tbody>
</table>
| | Continual | - High-dose inhaled corticosteroids  
| | Frequent | AND  
| | | - Long-acting inhaled beta₂-agonists  
| | | AND, if needed,  
| | | - Corticosteroid tablets or syrup long term (2 mg/kg/day, generally do not exceed 60 mg per day). (Make repeat attempts to reduce systemic corticosteroids and maintain control with high-dose inhaled corticosteroids.) |
| **Step 3** | **Moderate Persistent** | **Preferred treatments:** |
| | Daily | - Low-dose inhaled corticosteroids and long-acting inhaled beta₂-agonists  
| | > 1 night/week | OR  
| | | - Medium-dose inhaled corticosteroids.  
| | | **Alternative treatment:**  
| | | - Low-dose inhaled corticosteroids and either leukotriene receptor antagonist or theophylline.  
| | | No daily medication needed.  
| | | If needed (particularly in patients with recurring severe exacerbations):  
| | | **Preferred treatment:**  
| | | - Medium-dose inhaled corticosteroids and long-acting beta₂-agonists.  
| | | **Alternative treatment:**  
| | | - Medium-dose inhaled corticosteroids and either leukotriene receptor antagonist or theophylline.  
| **Step 2** | **Mild Persistent** | **Preferred treatment:** |
| | > 2/week but < 1x/day | - Low-dose inhaled corticosteroid (with nebulizer or MDI with holding chamber with or without face mask or DPI).  
| | > 2 nights/month | **Alternative treatment (listed alphabetically):**  
| | | - Cromolyn (nebulizer is preferred or MDI with holding chamber)  
| | | OR leukotriene receptor antagonist.  
| **Step 1** | **Mild Intermittent** | **No daily medication needed.** |
| | ≤ 2 days/week |  
| | ≤ 2 nights/month |  

#### Quick Relief

**All Patients**

- Bronchodilator as needed for symptoms. Intensity of treatment will depend upon severity of exacerbation.  
  - Preferred treatment: Short-acting inhaled beta₂-agonists by nebulizer or face mask and space/holding chamber  
  - Alternative treatment: Oral beta₂-agonist  
- With viral respiratory infection  
  - Bronchodilator q 4–6 hours up to 24 hours (longer with physician consult); in general, repeat no more than once every 6 weeks  
  - Consider systemic corticosteroid if exacerbation is severe or patient has history of previous severe exacerbations  
- Use of short-acting beta₂-agonists >2 times a week in intermittent asthma (daily, or increasing use in persistent asthma) may indicate the need to initiate (increase) long-term control therapy.

#### Step down

Review treatment every 1 to 6 months; a gradual stepwise reduction in treatment may be possible.

#### Step up

If control is not maintained, consider step up. First, review patient medication technique, adherence, and environmental control.

#### Goals of Therapy: Asthma Control

- Minimal or no chronic symptoms day or night  
- Minimal or no exacerbations  
- No limitations on activities; no school/parent’s work missed  
- Minimal use of short-acting inhaled beta₂-agonist (< 1x per day, < 1 canister/month)  
- Minimal or no adverse effects from medications

#### Note

- The stepwise approach is intended to assist, not replace, the clinical decisionmaking required to meet individual patient needs.  
- Classify severity: assign patient to most severe step in which any feature occurs.  
- There are very few studies on asthma therapy for infants.  
- Gain control as quickly as possible (a course of short systemic corticosteroids may be required); then step down to the least medication necessary to maintain control.  
- Provide parent education on asthma management and controlling environmental factors that make asthma worse (e.g., allergies and irritants).  
- Consultation with an asthma specialist is recommended for patients with moderate or severe persistent asthma. Consider consultation for patients with mild persistent asthma.
### Stepwise Approach for Managing Asthma in Adults and Children Older Than 5 Years of Age: Treatment

#### Classify Severity: Clinical Features Before Treatment or Adequate Control

<table>
<thead>
<tr>
<th>Symptoms/Day</th>
<th>PEF or FEV&lt;sub&gt;1&lt;/sub&gt;</th>
<th>Medications Required To Maintain Long-Term Control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Daily Medications</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Preferred treatment:</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- High-dose inhaled corticosteroids</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AND</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Long-acting inhaled beta&lt;sub&gt;2&lt;/sub&gt;-agonists</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AND, if needed,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Corticosteroid tablets or syrup long term (2 mg/kg/day, generally do not exceed 60 mg per day). (Make repeat attempts to reduce systemic corticosteroids and maintain control with high-dose inhaled corticosteroids.)</td>
</tr>
</tbody>
</table>

**Step 4**  
**Severe Persistent**
- Symptoms/Day
  - Continual
  - Frequent
- Symptoms/Night
  - > 1 night/week
- PEF or FEV<sub>1</sub> ≤ 60%
- PEF Variability > 30%

**Step 3**  
**Moderate Persistent**
- Symptoms/Day
  - Daily
  - > 2/week but < 1x/day
  - > 2 nights/month
- Symptoms/Night
  - > 2 nights/month
- PEF or FEV<sub>1</sub> ≥ 80%
- PEF Variability 20–30%

**Step 2**  
**Mild Persistent**
- Symptoms/Day
  - ≤ 2 days/week
  - ≤ 2 nights/month
- Symptoms/Night
  - ≤ 2 days/week
  - ≤ 2 nights/month
- PEF or FEV<sub>1</sub> ≥ 80%
- PEF Variability < 20%

**Step 1**  
**Mild Intermittent**
- Symptoms/Day
  - ≤ 2 days/week
  - ≤ 2 nights/month
- Symptoms/Night
  - ≤ 2 days/week
  - ≤ 2 nights/month
- PEF or FEV<sub>1</sub> ≥ 80%
- PEF Variability < 20%

#### Quick Relief  
**All Patients**
- Short-acting bronchodilator: 2–4 puffs short-acting inhaled beta<sub>2</sub>-agonists as needed for symptoms.
- Intensity of treatment will depend on severity of exacerbation; up to 3 treatments at 20-minute intervals or a single nebulizer treatment as needed. Course of systemic corticosteroids may be needed.
- Use of short-acting beta<sub>2</sub>-agonists >2 times a week in intermittent asthma (daily, or increasing use in persistent asthma) may indicate the need to initiate (increase) long-term control therapy.

#### Goals of Therapy: Asthma Control

- Minimal or no chronic symptoms day or night
- Minimal or no exacerbations
- No limitations on activities; no school/work missed
- Maintain (near) normal pulmonary function
- Minimal use of short-acting inhaled beta<sub>2</sub>-agonist (< 1x per day, < 1 canister/month)
- Minimal or no adverse effects from medications

#### Note

- The stepwise approach is meant to assist, not replace, the clinical decisionmaking required to meet individual patient needs.
- Classify severity: assign patient to most severe step in which any feature occurs (PEF is % of personal best; FEV<sub>1</sub> is % predicted).
- Gain control as quickly as possible (consider a short course of systemic corticosteroids); then step down to the least medication necessary to maintain control.
- Provide education on self-management and controlling environmental factors that make asthma worse (e.g., allergens and irritants).
- Refer to an asthma specialist if there are difficulties controlling asthma or if step 4 care is required. Referral may be considered if step 3 care is required.
Usual Dosages for Long-Term-Control Medications (see HMSA Formulary on next page)

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dosage Form</th>
<th>Adult Dose</th>
<th>Child Dose*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inhaled Corticosteroids</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(See Estimated Comparative Daily Dosages for Inhaled Corticosteroids.)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Systemic Corticosteroids</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methylprednisolone</td>
<td>2, 4, 8, 16, 32 mg tablets</td>
<td>7.5–60 mg daily in a single dose in a.m. or qod as needed for control</td>
<td>0.25–2 mg/kg daily in single dose in a.m. or qod as needed for control</td>
</tr>
<tr>
<td>Prednisolone</td>
<td>5 mg tablets, 5 mg/5 cc, 15 mg/5 cc</td>
<td>Short-course “burst” to achieve control: 40–60 mg per day as single or 2 divided doses for 3–10 days</td>
<td>Short-course “burst”: 1–2 mg/kg/day, maximum 60 mg/day for 3–10 days</td>
</tr>
<tr>
<td>Prednisone</td>
<td>1, 2.5, 5, 10, 20, 50 mg tablets; 5 mg/cc, 5 mg/5 cc</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Long-Acting Inhaled Beta2-Agonists** (Should not be used for symptom relief or for exacerbations. Use with inhaled corticosteroids.)

- Salmeterol
  - MDI 21 mcg/puff
  - DPI 50 mcg/blister
- Formoterol
  - DPI 12 mcg/single-use capsule

**Combined Medication**

- Fluticasone/Salmeterol
  - DPI 100, 250, or 500 mcg/50 mcg

**Cromolyn and Nedocromil**

- Cromolyn
  - MDI 1 mg/puff
  - Nebulizer 20 mg/ampule
- Nedocromil
  - MDI 1.75 mg/puff

**Leukotriene Modifiers**

- Montelukast
  - 4 or 5 mg chewable tablet
  - 10 mg tablet
- Zafirlukast
  - 10 or 20 mg tablet
  - 300 or 600 mg tablet
- Zileuton
  - 4 or 5 mg chewable tablet
  - 10 mg tablet

**Methylxanthines** (Serum monitoring is important [serum concentration of 5–15 mcg/mL at steady state]).

- Theophylline
  - Liquids, sustained-release tablets, and capsules

Estimated Comparative Daily Dosages for Inhaled Corticosteroids (see HMSA Formulary on next page)

<table>
<thead>
<tr>
<th>Drug</th>
<th>Low Daily Dose</th>
<th>Medium Daily Dose</th>
<th>High Daily Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Adult</td>
<td>Child*</td>
<td>Adult</td>
</tr>
<tr>
<td>Beclomethasone CFC</td>
<td>168–504 mcg</td>
<td>84–336 mcg</td>
<td>&gt; 840 mcg</td>
</tr>
<tr>
<td>42 or 84 mcg/puff</td>
<td>80–240 mcg</td>
<td>80–160 mcg</td>
<td>&gt; 480 mcg</td>
</tr>
<tr>
<td>Beclomethasone HFA</td>
<td>200–600 mcg</td>
<td>200–400 mcg</td>
<td>&gt; 1,200 mcg</td>
</tr>
<tr>
<td>40 or 80 mcg/puff</td>
<td>0.5 mg</td>
<td>1.0 mg</td>
<td>2.0 mg</td>
</tr>
<tr>
<td>Budesonide DPI</td>
<td>0.5 mg</td>
<td>1.0 mg</td>
<td>2.0 mg</td>
</tr>
<tr>
<td>200 mcg/inhalation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inhalation suspension for nebulization (child dose)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flunisolide</td>
<td>500–1,000 mcg</td>
<td>1,000–2,000 mcg</td>
<td>&gt; 2,000 mcg</td>
</tr>
<tr>
<td>250 mcg/puff</td>
<td>300–750 mcg</td>
<td>1,000–1,250 mcg</td>
<td></td>
</tr>
<tr>
<td>Fluricasone</td>
<td>88–264 mcg</td>
<td>264–660 mcg</td>
<td>&gt; 660 mcg</td>
</tr>
<tr>
<td>MDI: 44, 110, or 220 mcg/puff</td>
<td>88–176 mcg</td>
<td>160–320 mcg</td>
<td>&gt; 400 mg</td>
</tr>
<tr>
<td>DPI: 50, 100, or 250 mcg/inhalation</td>
<td>100–300 mcg</td>
<td>200–400 mcg</td>
<td>&gt; 400 mg</td>
</tr>
<tr>
<td>Triamcinolone acetonide</td>
<td>400–1,000 mcg</td>
<td>800–1,200 mcg</td>
<td>&gt; 2,000 mcg</td>
</tr>
<tr>
<td>100 mcg/puff</td>
<td>400–800 mcg</td>
<td>400–800 mcg</td>
<td></td>
</tr>
</tbody>
</table>

* Children ≤ 12 years of age
The following table shows the recommended medications for use in the treatment of asthma. These medications are preferred agents on the HMSA Select formulary and on the formulary for HMSA QUEST.

<table>
<thead>
<tr>
<th>Medications Table</th>
<th>GENERIC NAME</th>
<th>BRAND NAME</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inhaled corticosteroids</strong></td>
<td>flunisolide</td>
<td>Aerobid, Aerobid M</td>
</tr>
<tr>
<td></td>
<td>budesonide</td>
<td>Pulmicort</td>
</tr>
<tr>
<td></td>
<td>fluticasone</td>
<td>Flovent</td>
</tr>
<tr>
<td><strong>Cromolyn</strong></td>
<td>cromolyn</td>
<td>Intal MDI, generic</td>
</tr>
<tr>
<td><strong>Theophylline</strong></td>
<td>theophylline, immediate release</td>
<td><em>generic only</em></td>
</tr>
<tr>
<td></td>
<td>theophylline, timed release</td>
<td>Theo-24, Theochron, generic</td>
</tr>
<tr>
<td><strong>Leukotriene modifiers</strong></td>
<td>zafirlukast</td>
<td>Accolate</td>
</tr>
<tr>
<td></td>
<td>zileuton</td>
<td>Zyflo</td>
</tr>
<tr>
<td></td>
<td>montelukast</td>
<td>Singulair</td>
</tr>
<tr>
<td><strong>Short-acting inhaled beta_2-agonists</strong></td>
<td>albuterol</td>
<td><em>generic only</em></td>
</tr>
<tr>
<td></td>
<td>pirbuterol</td>
<td>Maxair, Maxair Autohaler</td>
</tr>
<tr>
<td><strong>Long-acting inhaled beta_2-agonists</strong></td>
<td>salmeterol</td>
<td>Serevent</td>
</tr>
<tr>
<td><strong>Long-acting oral beta_2-agonists</strong></td>
<td>albuterol, extended release</td>
<td><em>generic only</em></td>
</tr>
<tr>
<td><strong>Short-acting oral beta_2-agonists</strong></td>
<td>albuterol</td>
<td><em>generic only</em></td>
</tr>
<tr>
<td><strong>Combined medication</strong></td>
<td>fluticasone / salmeterol</td>
<td>Advair</td>
</tr>
</tbody>
</table>
These guidelines are intended as an educational reference and do not supersede the clinical judgment of the treating physician with respect to appropriate and necessary care for a particular patient. The clinical references from which these guidelines are taken are listed at the end of this document.

<table>
<thead>
<tr>
<th>ASSESSMENT</th>
<th>INDICATION</th>
<th>MEASUREMENT/VALUE</th>
<th>INTERVENTION</th>
<th>FOLLOW-UP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptoms*</td>
<td>Routinely.</td>
<td>Cough, episodic wheeze, chest tightness, shortness of breath.</td>
<td>Identify symptom etiology</td>
<td>Each visit.</td>
</tr>
<tr>
<td>Smoking Status1,7</td>
<td>All asthma patients.</td>
<td>Ask all patients if they smoke. If yes, then smoking cessation should be addressed. Ask patients about exposure to secondhand smoke.</td>
<td>Follow the Five A's</td>
<td>Each visit.</td>
</tr>
<tr>
<td>Environmental Control</td>
<td>All patients with allergies.</td>
<td>Identify factors that contribute to asthma severity. Patient to complete self-assessment of environmental factors that may trigger asthma symptoms. Patient to record symptoms daily over two to three-week periods to identify triggers.</td>
<td>Educate patients regarding symptom control.</td>
<td>Initially and as indicated.</td>
</tr>
<tr>
<td>Medications1,6</td>
<td>All receiving pharmacological therapy.</td>
<td>Document current medications. Document control of symptoms.</td>
<td>Educate on indications, frequency, dosage and possible side effects.</td>
<td>Each visit.</td>
</tr>
<tr>
<td>Spirometry1,5</td>
<td>Initially to establish airflow obstruction and obstruction reversibility. Abnormal: FEV1 &lt; 80% of predicted normal values (indicates airflow obstruction) and FEV1/FVC &lt; 65% of predicted normal values (indicates airway obstruction).</td>
<td>Evaluate patient on the morning of spirometry results and the effect of shortacting Beta2-agonist.</td>
<td>Other symptoms and peak flow rates have stabilized. More often as indicated by unstable asthma.</td>
<td></td>
</tr>
<tr>
<td>Goals of Asthma Therapy1</td>
<td>All asthma patients.</td>
<td>Identify frequency of asthma symptoms and exacerbations. AllerGastric resistance is a modifiable factor that can be improved.</td>
<td>Collaborative development of asthma therapy goals.</td>
<td>Initially and as conditions warrant change in therapy and/or goals.</td>
</tr>
<tr>
<td>Asthma Action Plan1,3</td>
<td>All asthma patients.</td>
<td>Establish action plan and specific recommendations of the plan.</td>
<td>Review patient and provide written instructions on use of plan. Have patient explain exact steps to take when PEFR zones and symptoms warrant action.</td>
<td>Each visit.</td>
</tr>
<tr>
<td>Assess for Risk of Fatal Asthma Attack1,4</td>
<td>Patients with history of severe exacerbations requiring emergency visit or hospitalization. Patients with contraindications (pneumonia, chronic bronchitis, CHF, nasal polyps and history of sensitivity to aspirin or nonsteroidal anti-inflammatories).</td>
<td>Evaluate ways to decrease risk of fatal asthma attack.</td>
<td>Educate for early warning signs.</td>
<td>Each visit.</td>
</tr>
<tr>
<td>Influenza Vaccination1</td>
<td>All asthma patients unless allergic.</td>
<td>Document last immunization</td>
<td>Administer and document every year.</td>
<td>Annually.</td>
</tr>
</tbody>
</table>

* Recommended pharmacotherapies for smoking cessation include: First line – Bupropion SR, nicotine gum, nicotine inhaler, nicotine nasal spray and nicotine patch. Second line – Clonidine and Nortriptyline. Over-the-counter nicotine patches.
### ASSESSMENT

<table>
<thead>
<tr>
<th>Peak Expiratory Flow Rate (PEFR) Monitoring 1,2</th>
</tr>
</thead>
<tbody>
<tr>
<td>All asthma patients.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medicine Delivery Device 1,2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients receiving inhalated medications with metered-dose inhalers (MDIs), gas-powered nebulizers (GPNs), dry powder inhaler (DPI), spacers and holding chambers.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Specialty Referral 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consider specialty referral if patients meet criteria:</td>
</tr>
<tr>
<td>• Problematic differential diagnosis.</td>
</tr>
<tr>
<td>• Requiring allergy testing.</td>
</tr>
<tr>
<td>• Severe persistent symptoms or requiring more than four treatments of oral steroids in one year.</td>
</tr>
<tr>
<td>• Younger than three years, requiring step 3 or 4 care.</td>
</tr>
<tr>
<td>• Not meeting goals of asthma therapy after 3 to 6 months.</td>
</tr>
<tr>
<td>• Occurrence of life-threatening asthma exacerbation.</td>
</tr>
<tr>
<td>• Exacerbations associated with multiple infections.</td>
</tr>
</tbody>
</table>

### INDICATION

- All children less than or equal to 23 months.
- People age 24-59 months with asthma should NOT receive vaccination unless on high dose corticosteroid therapy.

### MEASUREMENT/VALUE

- Document last immunization.
- Establish personal best number (PBN). Then calculate:
  - Green zone = 80 to 100% PBN
  - Yellow zone = 50 to 79% of PBN
  - Red zone = less than 50% PBN (Most PEFR meter instructions provide directions to establish PBN)
  - Educate on tracking PEFR by daily and correlation of change in numbers to symptom severity.

### INTERVENTION

- All children less than or equal to 23 months receive 4 routine doses.
- Children age 24-59 months who have asthma and are on high dose corticosteroid therapy should receive the vaccine if not previously vaccinated.

- Establish personal best number (PBN). Then calculate:
  - Green zone = 80 to 100% PBN
  - Yellow zone = 50 to 79% of PBN
  - Red zone = less than 50% PBN

- Educate patient on importance of monitoring PEFR, of establishing personal best number, of the green/yellow/red zone indications and of taking appropriate action.
- Observe patient’s PEFR technique.
- Educate on tracking PEFR by daily and correlation of change in numbers to symptom severity.
- Demonstrate proper technique and then observe that patient technique is correct.
- Review proper cleaning, care and storage of delivery device.
- Consider use of GPN, spacer or holding chamber for those who cannot properly use an MDI.
- Inform patient of indications for specialty referral, including benefits of referral.

### FOLLOW-UP

- Routine schedule is four doses, one at each of these ages:
  - 2 months
  - 4 months
  - 6 months
  - 12 to 15 months
- Children age 24-59 months who are on high dose corticosteroids should receive a single dose of vaccine.
- Each visit.
- Each visit or as indicated.
- After specialty referral has taken place.

### REFERENCES:


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# Care Guide for Asthma

## Clinical Features Before Treatment

<table>
<thead>
<tr>
<th>Step</th>
<th>Daytime Symptoms</th>
<th>Nighttime Symptoms</th>
<th>Lung Function</th>
<th>Long-term Control</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Step 4</strong></td>
<td>Severe Persistent</td>
<td>Frequent</td>
<td><strong>FEV₁ or PEF &lt; 60% predicted</strong></td>
<td><strong>Preferred treatment:</strong>&lt;br&gt;• High-dose inhaled corticosteroids AND&lt;br&gt;• Medium- or long-acting inhaled beta₂-agonists AND, if needed,&lt;br&gt;• Oral leukotriene modifier or theophylline.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>PEF Variability &gt; 30%</strong></td>
<td>(Makes repeat attempts to reduce systemic corticosteroids and maintain control with high-dose inhaled corticosteroids.)</td>
</tr>
<tr>
<td><strong>Step 3</strong></td>
<td>Moderate Persistent</td>
<td>&gt; 1 night a week</td>
<td><strong>FEV₁ or PEF &gt; 60% – &lt; 80% predicted</strong></td>
<td><strong>Preferred treatment:</strong>&lt;br&gt;• Low-to-medium dose inhaled corticosteroids and long-acting inhaled beta₂-agonists.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>PEF Variability &gt; 30%</strong></td>
<td><strong>Alternative treatment (listed alphabetically):</strong>&lt;br&gt;• Increase inhaled corticosteroids within medium-dose range OR&lt;br&gt;• Low-to-moderate dose inhaled corticosteroids and other leukotriene modifier or theophylline.</td>
</tr>
<tr>
<td><strong>Step 2</strong></td>
<td>Mild Persistent</td>
<td>&gt; 2 times a week but &lt; 1 time a day</td>
<td><strong>FEV₁ or PEF &gt; 80% predicted</strong></td>
<td><strong>Preferred treatment:</strong>&lt;br&gt;• Low-dose inhaled corticosteroids.</td>
</tr>
</tbody>
</table>
| | | | **PEF Variability 20 – 30%** | **Alternative treatment (listed alphabetically):**
| | | | | • Increase inhaled corticosteroids within medium-dose range and add either leukotriene antagonist or theophylline. |
| **Step 1** | Mild Intermittent | > 2 times a week | **FEV₁ or PEF > 80% predicted** | **Preferred treatment:**<br>• Low-dose inhaled corticosteroid (with nebulizer or MDI with holding chamber with or without face mask or DPI). |
| | | | **PEF Variability < 20%** | **Alternative treatment (listed alphabetically):**<br>• Cromolyn (nebulizer is preferred or MDI with holding chamber) OR leukotriene receptor antagonist. |

## Treatment

<table>
<thead>
<tr>
<th>Step</th>
<th>Daytime Symptoms</th>
<th>Nighttime Symptoms</th>
<th>Lung Function</th>
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| | | | | • Cromolyn (nebulizer is preferred or MDI with holding chamber) OR leukotriene receptor antagonist. |

## Quick Relief

**All Patients**

- **Short-acting bronchodilators:** 2–4 puff short-acting inhaled beta₂-agonists as needed for symptoms.
- **Intensity of treatment will depend on severity of exacerbation:** up to 3 treatments at 20-minute intervals or a single nebulizer treatment as needed.
- **Course of systemic corticosteroids may be needed.**
- **Use of short-acting beta₂-agonists > 2 times a week in intermittent asthma (daily, or increasing use in persistent asthma) may indicate the need to initiate (increase) long-term control therapy.**

**Infants and Children Under 5 Years of Age**

- **Bronchodilator as needed for symptoms.**
- **Intensity of treatment will depend upon severity of exacerbation.**
- **Preferred treatment:** Short-acting inhaled beta₂-agonists by nebulizer or face mask and spacer/holding chamber OR sustained release theophylline to serum concentration of 5–15 mcg/mL.
- **Alternative treatment (listed alphabetically):**
  - • Oral leukotriene receptor antagonist OR leukotriene inhibitor or bronchodilator with holding chamber with or without face mask or DPI.
  - • Low-dose inhaled corticosteroids.

**With viral respiratory infection**

- **Bronchodilator q 4–6 hours up to 24 hours (longer with physician consultation).**
- **Repeat no more than once every 6 weeks.**
- **Consider systemic corticosteroid if exacerbation is severe or patient has history of previous severe exacerbations.**
- **Use of short-acting beta₂-agonists > 2 times a week in intermittent asthma (daily, or increasing use in persistent asthma) may indicate the need to initiate (increase) long-term control therapy.**

---

GOALS OF THERAPY: ASTHMA CONTROL

- Maintain (near) normal pulmonary function in 1 year of age: 16 mg/kg/day
- > 1 year of age: 4 mg/kg/day
- Children < 1 year of age: 0.2 (age in weeks)
- Starting dose: 10 mg/kg/day; usual max: < 1 year of age: 0.2 (age in weeks) ≥ 1 year of age: 16 mg/kg/day
- Starting dose: 10 mg/kg/day; usual max: < 1 year of age: 0.2 (age in weeks) ≥ 1 year of age: 16 mg/kg/day
- There are very few studies on asthma therapy for infants.
- Provide education on self-management and controlling environmental factors that make asthma worse (e.g., allergies and irritants).
- For children < 5 years, provide parental education on asthma management and controlling environmental factors that make asthma worse (e.g., allergies and irritants).

*The presence of one or more factors of severity is sufficient to place a patient in that category. An individual should be assigned to the most severe step in which any feature occurs. The characteristics noted in this figure are general and may overlap because asthma is highly variable. Furthermore, an individual's classification may change over time.

**Patients at any level of severity can have mild, moderate or severe exacerbations. Some patients with intermittent asthma experience severe and life-threatening exacerbations separated by long periods of normal lung function and no symptoms.

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Introduction

Allergic rhinitis is a common illness affecting an estimated 20-40 million Americans, and resulting in 10 million lost days of school or work each year. Often caused by pollen from trees, grass or weeds, it is most commonly known as hay fever. In temperate climates, hay fever subsides with the onset of cold weather. Perennial allergic rhinitis, however, occurs year-round and is caused by indoor allergens such as dust, mites, mold spores, and animal dander.

Goals/Desired Outcomes

- Increase the use of prophylactic medications for patients with seasonal allergic rhinitis. One possible measurable result is the percentage of patients with seasonal allergic rhinitis prescribed prophylactic medication
- Decrease use of injectable corticosteroid therapy for patients with allergic rhinitis. One possible measurable result is the percentage of patients with allergic rhinitis being treated with injectable corticosteroids.

Diagnosis

The history and physical (H&P) examination is the starting point in establishing the diagnosis of rhinitis.

Table 1: Diagnostic Indicators

<table>
<thead>
<tr>
<th>ALLERGIC ETIOLOGY</th>
<th>NONALLERGIC RHINITIS</th>
<th>ALLERGIC AND NONALLERGIC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Puritis of the eyes, nose, palate, ears</td>
<td>Sensitivity to smoke, perfume, weather changes and environmental irritants</td>
<td>Perennial symptoms</td>
</tr>
<tr>
<td>Watery rhinorrhea</td>
<td>History of previous negative allergy testing</td>
<td>Episodic symptoms</td>
</tr>
<tr>
<td>Sneezing</td>
<td>Overuse of topical decongestants</td>
<td>Nasal congestion</td>
</tr>
<tr>
<td>Seasonal symptoms</td>
<td>Adult onset of symptoms</td>
<td>History of frequent sinus infections/chronic sinusitis</td>
</tr>
<tr>
<td>Family history allergies</td>
<td>Nasal crusting or drying</td>
<td></td>
</tr>
<tr>
<td>Sensitivity to specific allergens, especially dust, animals, pollen, and mold</td>
<td>Facial pain</td>
<td></td>
</tr>
</tbody>
</table>

Evaluation

A patient’s history should include evaluation of the quality of life and specific factors that would define the classification of the rhinitis. The physical exam should include ears, eyes, nose, and mouth. Nasal cytology may be valuable to differentiate allergic rhinitis or nonallergic rhinitis eosinophilia syndrome (NARES) from nonallergic rhinitis.
**History of present illness:**
- Congestion or obstruction
- Rhinorrhea (anterior nasal discharge)
- Pruritis of nose or eyes
- Sneezing, posterior nasal discharge with or without cough
- Sinus pressure/pain
- Snoring
- Episodic (seasonal or perennial symptoms)
- Specific triggers
- Pregnancy
- Current medications such as topical decongestants
- Hormones
- Antihypertensives
- Antibiotics
- Age at onset of symptoms
- Current and previous treatments for rhinitis

**Family history:**
- Asthma
- Rhinitis
- Atopic dermatitis

**Past medical history:**
- History of trauma or facial/sinus surgery

**Relevant medical conditions:**
- Asthma
- Dermatitis
- Chronic or recurrent otitis media, and history of polyps and ASA/NSAID sensitivity
- Chronic sinusitis

**Social and environmental history:**
- Occupational exposures
- Home exposures
- Active and passive smoking exposure, and illicit drug exposure

---

**Table 2: History**

<table>
<thead>
<tr>
<th>History of present illness:</th>
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</tr>
</thead>
<tbody>
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<td>• Snoring</td>
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</thead>
<tbody>
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<td>• Active and passive smoking exposure, and illicit drug exposure</td>
</tr>
<tr>
<td>• Home exposures</td>
<td></td>
</tr>
</tbody>
</table>

---

**Table 3: Physical Conditions**

**Nose:**
- Swollen nasal turbinates (may be boggy, bluish or pale, hyperemic or purplish red); note size and color
- Clear, cloudy or colored rhinorrhea
- Nasal septal deviation or structural abnormality
- Nasal polyps
- Nasal crease from “allergic salute”
- Sneezing
- Mouth breathing
- Unilateral obstruction
- Foreign body

**Eyes:**
- Conjunctivitis
- Allergic “shiners” (dark circles under the eyes from venous stasis)
- Dennie’s lines (lower eyelid crease)
- Periorbital edema

**Ears:**
- Acute otitis media or otitis media with effusion (suggesting associated Eustachian tube dysfunction)

**Lungs:**
- Wheezing or prolonged expiratory phase (suggesting associated asthma)

**Other:**
- Allergic mannerisms
- Sneezing
- Mouth breathing
- Unilateral obstruction

**Skin:**
- Atopic dermatitis
Consultation
Consultation is most appropriate for patients with severe or atypical symptoms and those who are not responding as expected to appropriate medical care. Results of consultation with an ENT or allergist may further define the classification and rule out polyps and other nasal pathology. Allergists may also conduct skin testing to better define potential specific allergens.

Treatment
Avoidance of triggers is the best treatment for any allergy whenever possible. Controls and specific treatments based on the patient’s classification should include an avoidance of inciting factors (dust, carpets, pollen, etc.) and the treatment of infections as obvious first steps in effective management prior to using medication specifically targeting rhinitis.

Pharmacological management / Chronic and first-line medications
Nasal steroids
These agents are recommended as first-line therapy for both allergic and nonallergic rhinitis that is chronic, frequently recurrent, and which have a significant influence on the patient’s quality of life. It takes several days for the nasal steroids to reach maximal effect. They are administered on a continuous regimen and should not be used as a rescue medication. The importance of the delay in effectiveness should be stressed to the patient.

Oral antihistamines
Non-sedating oral antihistamines may be used as first-line therapy or in conjunction with other agents.

Intranasal antihistamines
Intranasal antihistamine may be useful as first-line treatment particularly for mild and intermittent symptoms. It does not reduce nasal congestion. The medication has a bitter taste; there may be significant systemic absorption that may result in sedation.

Alternative and acute medications
Oral decongestants
These medications may be used for acute symptoms or in combination with first-line medication. Use should be limited in patients with hypertension, angina pectoris and arrhythmia. Side effects may include insomnia and excessive nervousness.

Nasal decongestants
Topical sympathomimetics are useful for acute relief but should not be used for more than two to three days due to the potential rebound effect and exacerbation of nasal congestion.
Oral steroids
A short course of oral steroids is appropriate for severe or intractable nasal symptoms or significant nasal polyposis.

Intranasal cromolyn
Intranasal cromolyn is effective in some patients in controlling allergic rhinitis and can be used as first-line or adjuvant therapy.

Intranasal anticholinergics
These agents may be used for acute relief of rhinorrhea. Intranasal anticholinergics do not reduce other symptoms. They would be second-line agents for select patients.

Oral antileukotrienes
These agents may be effective, but recommendations await further studies.

Allergen immunotherapy
A treatment option for selected patients with allergic rhinitis. The decision to use immunotherapy should be based on the severity of symptoms and the response to other medications.

Sedating antihistamines
Sedating antihistamines may be used for relief of acute symptoms. Chronic use may influence performance. Recent studies suggest that first generation (sedating) antihistamines can cause impaired performance even when a patient is unaware of sedation. Sedating antihistamines are not recommended for children and adults who drive or participate in activities required to be performed at an alert functional level. The sedative effect can last up to 24 hours. Antihistamines are effective for most allergic symptoms, but have little objective effect on nasal congestion.
The following table shows the recommended medications for use in the treatment of rhinitis. These medications are preferred agents on the HMSA Select formulary and on the formulary for HMSA QUEST.

**Medications Table**

<table>
<thead>
<tr>
<th><strong>GENERIC NAME</strong></th>
<th><strong>BRAND NAME</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>First-line nasal steroids</td>
<td></td>
</tr>
<tr>
<td>Flunisolide</td>
<td>Nasalide, Nasarel</td>
</tr>
<tr>
<td>Belomethasone dipropionate</td>
<td>Vancenase AQ</td>
</tr>
<tr>
<td>Budesonide</td>
<td>Rhinocort AQ</td>
</tr>
<tr>
<td>Fluticasone propionate</td>
<td>Flonase</td>
</tr>
<tr>
<td>Mometasone</td>
<td>Nasonex</td>
</tr>
<tr>
<td>Triamcinolone</td>
<td>Nasacort AQ</td>
</tr>
<tr>
<td>Non-sedating or less sedating antihistamines</td>
<td></td>
</tr>
<tr>
<td>Fexofenadine</td>
<td>Allegra</td>
</tr>
<tr>
<td>Cetirizine syrup</td>
<td>Zyrtec syrup</td>
</tr>
<tr>
<td>Nasal antihistamines</td>
<td></td>
</tr>
<tr>
<td>Azelastine</td>
<td>Astelin</td>
</tr>
<tr>
<td>Nasal cromolyn</td>
<td></td>
</tr>
<tr>
<td>Cromolyn sodium</td>
<td>Nasalcrom (on QUEST only)</td>
</tr>
<tr>
<td>Nasal decongestants</td>
<td><em>available over the counter</em></td>
</tr>
<tr>
<td>Phenylephrine</td>
<td></td>
</tr>
<tr>
<td>Oxymetazoline</td>
<td><em>available over the counter</em></td>
</tr>
<tr>
<td>Oral decongestants</td>
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</tr>
<tr>
<td>Pseudoephedrine</td>
<td></td>
</tr>
<tr>
<td>Combination non-sedating antihistamine and decongestant</td>
<td><em>available over the counter</em></td>
</tr>
<tr>
<td>Fexofenadine / pseudoephedrine</td>
<td></td>
</tr>
<tr>
<td>Nasal anti-cholinergic</td>
<td>Ipratropium</td>
</tr>
<tr>
<td></td>
<td>*generic only</td>
</tr>
</tbody>
</table>

*generic on QUEST only
Chronic Obstructive Pulmonary Disease

Introduction
Chronic Obstructive Pulmonary Disease (COPD) is a disease state characterized by airflow limitation that is not fully reversible. The airflow limitation is usually both progressive and associated with an abnormal inflammatory response of the lungs to noxious particles or gases. This definition does not use the terms chronic bronchitis and emphysema and excludes asthma (reversible airflow limitation). Symptoms of COPD include:
- Cough
- Sputum production
- Dyspnea on exertion.

Goals/Desired Outcomes
The purpose of this guideline is to increase awareness of COPD and consequently decrease morbidity and mortality. The goals of effective COPD management include the following:
- Prevent disease progression
- Relieve symptoms
- Improve exercise tolerance
- Improve health status
- Prevent and treat complications
- Prevent and treat exacerbations
- Reduce mortality
- Prevent or minimize side effects from treatment
- Cessation of cigarette smoking should be included as a goal throughout the management program.

Diagnosis
A diagnosis of COPD should be considered in any individual who presents characteristic symptoms and a history of exposure to risk factors for the disease, especially cigarette smoking (see key indicators below). The diagnosis should be confirmed by spirometry, and where spirometry is unavailable, the diagnosis of COPD should be made using all available tools. Clinical symptoms and signs (abnormal shortness of breath and increased forced expiratory time) can be used to help with the diagnosis. A low peak flow is consistent with COPD but has poor specificity since it can be caused by other lung diseases and by poor performance. In the interest of improving the accuracy of a diagnosis of COPD, every effort should be made to provide access to standardized spirometry.

Key Indicators for Considering a COPD Diagnosis
- Chronic cough: Present intermittently or every day. Often present throughout the day; seldom only nocturnal.
- Chronic sputum production: Any pattern of chronic sputum production may indicate COPD.
**COPD 2003 Highlights (continued from page 3-1)**

- The most important risk factor for COPD is cigarette smoking. Pipe, cigar, and other types of tobacco smoking popular in many countries are also risk factors for COPD. At every possible opportunity individuals who smoke should be encouraged to quit.
- A diagnosis of COPD should be considered in any individual with symptoms and a history of exposure to risk factors. The diagnosis should be confirmed by spirometry.
- A COPD management program includes four components: assess and monitor disease, reduce risk factors, manage stable COPD, and manage exacerbations.
- Pharmacologic treatment can improve and prevent symptoms, reduce the frequency and severity of exacerbations, improve health status, and improve exercise tolerance.
- Patient education can help improve skills, ability to cope with illness, and health status. It is an effective way to accomplish smoking cessation, initiate discussions and understanding of advance directives and end-of-life issues, and improve responses to acute exacerbations.
- COPD is often associated with exacerbations of symptoms.

<table>
<thead>
<tr>
<th>STAGE</th>
<th>CHARACTERISTICS</th>
</tr>
</thead>
<tbody>
<tr>
<td>0: At Risk</td>
<td>- Normal spirometry</td>
</tr>
<tr>
<td></td>
<td>- Chronic symptoms (cough, sputum, production)</td>
</tr>
<tr>
<td>I. Mild COPD</td>
<td>- FEV,FVC &lt; 70%</td>
</tr>
<tr>
<td></td>
<td>- 30% ≤ FEV₁ ≤ 80% predicted</td>
</tr>
<tr>
<td></td>
<td>- with or without chronic symptoms (cough, sputum, production)</td>
</tr>
<tr>
<td>II. Moderate COPD</td>
<td>- FEV,FVC &lt; 70%</td>
</tr>
<tr>
<td></td>
<td>- 30% ≤ FEV₁ ≤ 80% predicted (II: 50% ≤ FEV₁ &lt; 80% predicted)</td>
</tr>
<tr>
<td></td>
<td>- with or without chronic symptoms (cough, sputum, production)</td>
</tr>
<tr>
<td>III. Severe COPD</td>
<td>- FEV,FVC &lt; 70%</td>
</tr>
<tr>
<td></td>
<td>- 30% ≤ FEV₁ ≤ 50% predicted</td>
</tr>
<tr>
<td></td>
<td>- with or without chronic symptoms (cough, sputum, production)</td>
</tr>
<tr>
<td>IV. Very Severe COPD</td>
<td>- FEV,FVC &lt; 70%</td>
</tr>
<tr>
<td></td>
<td>- FEV₁ &lt; 30% predicted or FEV₁ &lt; 50% predicted plus respiratory failure</td>
</tr>
<tr>
<td></td>
<td>- or clinical signs of right heart failure</td>
</tr>
</tbody>
</table>

**Table 1: Classification of COPD by Severity (2003 Update)**
• Acute bronchitis: Repeated episodes.
• Dyspnea that is:
  - Progressive (worsens over time)
  - Persistent (present every day)
  - Worse on exercise
  - Worse during respiratory infections
• History of exposure to risk factors:
  - Tobacco smoke (including popular local preparations)
  - Occupational dusts and chemicals
  - Smoke from home cooking and heating fuel.

When performing spirometry, measure:
• Forced Vital Capacity (FVC) and
• Forced Expiratory Volume in one second (FEV₁)

Calculate the FEV₁/FVC ratio. Spirometric results are expressed as % predicted using appropriate normal values for the person’s sex, age, and height.

**Classification of COPD by Severity**

**Stage 0. At Risk** - Chronic cough and sputum production; lung function is still normal.

**Stage I. Mild COPD** - Mild airflow limitation (FEV₁/FVC < 70% but FEV₁ ≥ 80 % predicted) and usually, but not always, chronic cough and sputum production. At this stage, the individual may not be aware that his or her lung function is abnormal.

**Stage II. Moderate COPD** - Worsening airflow limitation (50% ≤ FEV₁ < 80% predicted), and usually the progression of symptoms, with shortness of breath typically developing on exertion.

**Stage III. Severe COPD** - Further worsening of airflow limitation (30% ≤/ FEV₁ < 50% predicted), increased shortness of breath, and repeated exacerbations that have an impact on patient’s quality of life. Exacerbations of symptoms, which have an impact on a patient’s quality of life and prognosis, are especially seen in patients with FEV₁< 50% predicted.

**Stage IV. Very Severe COPD** - Severe airflow limitation (FEV₁ < 30% predicted) or the presence of chronic respiratory failure. Patients may have very severe (Stage IV) COPD even if the FEV₁ is > 30% predicted, whenever these complications are present. At this stage, quality of life is very appreciably impaired and exacerbations may be life-threatening.

**Early Detection & Treatment**

• Prevent disease progression
• Relieve symptoms
• Improve exercise tolerance and health status
• Prevent and treat exacerbations and complications
• Reduce mortality and minimize treatment side effects
• Initiate early, regular treatment with inhaled bronchodilators to reduce COPD symptoms and prevent the physical and mental complications associated with COPD exacerbations
Differential Diagnosis
A major differential diagnosis is asthma. In some patients with chronic asthma, a clear distinction from COPD is not possible using current imaging and physiological testing techniques. In these patients, current management is similar to that of asthma. Other potential diagnoses are usually easier to distinguish from COPD.

Treatment
The following four components comprise a COPD management program intended to increase awareness of COPD and consequently decrease morbidity and mortality:
1. Assess and monitor disease
2. Reduce risk factors
3. Manage stable COPD
4. Manage exacerbations

Component 1: Assess and monitor disease
A detailed medical history of a new patient known or thought to have COPD should assess:
- Exposure to risk factors, including intensity and duration.
- Past medical history, including asthma, allergy, sinusitis or nasal polyps, respiratory infections, and other respiratory diseases.
- Family history of COPD or other chronic respiratory disease.
- Pattern of symptom development.
- History of exacerbations or previous hospitalizations for respiratory disorder.
- Presence of comorbidities, such as heart disease and rheumatic disease, that may also contribute to restriction of activity.
- Appropriateness of current medical treatments.
- Impact of disease on patient's life, including limitation of activity; missed work and economic impact; effect on family routines; and feelings of depression or anxiety.
- Social and family support available to the patient.
- Possibilities for reducing risk factors, especially smoking cessation.

In addition to spirometry, the following other tests should be undertaken for the assessment of a patient with Moderate (Stage II), Severe (Stage III), and Very Severe (Stage IV) COPD.
- Bronchodilator reversibility testing to rule out a diagnosis of asthma and guide initial treatment decisions.
- Inhaled glucocorticosteroid trial (6 weeks to 3 months) to identify patients with airflow limitation that is responsive to inhaled glucocorticosteroid treatment. If
objective benefit is not demonstrated, inhaled glucocorticosteroid should be discontinued.

- Chest X-ray is seldom diagnostic in COPD but valuable to exclude alternative diagnoses, e.g., pulmonary tuberculosis.
- Arterial blood gas measurement to be performed in patients with FEV₁ < 40% predicted or with clinical signs suggestive of respiratory failure or right heart failure. The major clinical sign of respiratory failure is cyanosis. Clinical signs of right heart failure include ankle edema and an increase in the jugular venous pressure.
- Alpha-1 antitrypsin deficiency screening to be performed when COPD develops in patients under 45, or in patients with a strong family history of COPD.

COPD is usually a progressive disease. Lung function can be expected to worsen over time, even with the best available care. Symptoms and lung function should be monitored to follow the development of complications, to guide treatment, and to facilitate discussion of management options with patients.

Component 2: Reduce risk factors

Smoking cessation is the single most effective – and cost-effective – intervention to reduce the risk of developing COPD and slow its progression. Even a brief, 3-minute period of counseling to urge a smoker to quit can be effective, and at a minimum this should be done for every smoker at every visit. More intensive strategies increase the likelihood of sustained quitting.

Pharmacotherapy (nicotine replacement and/or bupropion) is recommended when counseling is not sufficient to help patients stop smoking. Special consideration should be given before using pharmacotherapy in people smoking fewer than 10 cigarettes per day, pregnant women, adolescents, and those with medical contraindications (unstable coronary artery disease, untreated peptic ulcer, and recent myocardial infarction or stroke for nicotine replacement; and history of seizures for bupropion).

Smoking Prevention. Encourage comprehensive tobacco-control policies and programs with clear, consistent, and repeated nonsmoking messages. Work with government officials to pass legislation to establish smoke-free schools, public facilities, and work environments and encourage patients to keep smoke-free homes.

Occupational Exposures. Emphasize primary prevention, which is best achieved by elimination or reduction of exposures to various substances in the workplace. Secondary prevention, achieved through surveillance and early detection, is also important.

Indoor and Outdoor Air Pollution. Implement measures to reduce or avoid indoor air pollution from biomass fuel, burned for cooking and heating in poorly ventilated dwellings.
Advise patients to monitor public announcements of air quality and, depending on the severity of their disease, avoid vigorous exercise outdoors or stay indoors altogether during pollution episodes.

**Figure 1: Therapy**

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Old Gold 0: At Risk</th>
<th>I: Mild</th>
<th>IIA: Moderate</th>
<th>IIIB: Severe</th>
<th>III: Severe</th>
<th>IV: Very Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Gold</td>
<td>0: At Risk</td>
<td>I: Mild</td>
<td>II: Moderate</td>
<td>III: Severe</td>
<td>IV: Very Severe</td>
<td></td>
</tr>
<tr>
<td>FEV₁/FVC &lt; 70%</td>
<td>• FEV₁/FVC &lt; 70%</td>
<td>• FEV₁/FVC &lt; 70%</td>
<td>• FEV₁/FVC &lt; 70%</td>
<td>• FEV₁/FVC &lt; 70%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exposure to risk factors</td>
<td>• FEV₁ ≥ 80%</td>
<td>• FEV₁ ≥ 80%</td>
<td>• FEV₁ ≥ 80%</td>
<td>• FEV₁ ≥ 80%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal spirometry</td>
<td>• With or without symptoms</td>
<td>• With or without symptoms</td>
<td>• With or without symptoms</td>
<td>• With or without symptoms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Avoidance of risk factor(s); influenza vaccination</td>
<td>Add short-acting bronchodilator when needed</td>
<td>Add regular treatment with one or more long-acting bronchodilators Add rehabilitation</td>
<td>Add inhaled glucocorticosteroids if repeated exacerbations</td>
<td>Add long-term oxygen if chronic respiratory failure Consider surgical treatment</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Component 3: Manage Stable COPD**

Management of stable COPD should be guided by the following general principles:

- Determine disease severity on an individual basis by taking into account the patient’s symptoms, airflow limitation, frequency and severity of exacerbations, complications, respiratory failure, comorbidities, and general health status.
- Implement a stepwise treatment plan that reflects this assessment of disease severity.
- Choose treatments according to national and cultural preferences, the patient’s skills and preferences, and the local availability of medications.

Patient education can help improve skills, ability to cope with illness, and health status. It is an effective way to accomplish smoking cessation, initiate discussions and understanding of advance directives and end-of-life issues, and improve responses to acute exacerbations.

Pharmacologic treatment (Figure 1) can improve and prevent symptoms, reduce the frequency and severity of exacerbations, improve health status, and improve exercise tolerance. Bronchodilators. These medications are central to symptom management in COPD.

- Give “as-needed” to relieve intermittent or worsening symptoms, and on a regular basis to prevent or reduce persistent symptoms.
The choice between $\beta_2$-agonists, anticholinergics, methylxanthines, and combination therapy depends on the availability of medications and each patient's individual response in terms of both symptom relief and side effects.

Regular treatment with long-acting bronchodilators is more effective and convenient than treatment with short-acting bronchodilators, but more expensive.

Combining drugs with different mechanisms and durations of action may increase the degree of bronchodilation for equivalent or lesser side effects.

Theophylline is effective in COPD, but due to its potential toxicity, inhaled bronchodilators are preferred when available.

Regular nebulized bronchodilator therapy for a stable patient is not appropriate unless it has been shown to be better than conventional doses by metered dose inhaler.

**Glucocorticosteroids.** Regular treatment with inhaled glucocorticosteroids is only appropriate for patients with:

- symptomatic improvement and a documented spirometric response to inhaled glucocorticosteroids or
- an FEV$_1$ < 50% predicted and repeated exacerbations (for example, 3 in the last three years).

Prolonged treatment with inhaled glucocorticosteroids may relieve symptoms in this carefully selected group of patients but does not modify the long-term decline in FEV$_1$. The dose-response relationships and long-term safety of inhaled glucocorticosteroids in COPD are not known. Long-term treatment with oral glucocorticosteroids is not recommended.

**Vaccines.** Influenza vaccines reduce serious illness and death in COPD patients by 50%. Give once (in autumn) or twice (in autumn and winter) each year. There is no evidence for recommending the general use of pneumococcal vaccine for COPD.

**Antibiotics.** Not recommended except for treatment of infectious exacerbations and other bacterial infections.

**Mucolytic (mucokinetic, mucoregulator) agents.** Patients with viscous sputum may benefit from mucolytics, but overall benefits are very small. Use is not recommended.

**Antitussives.** Regular use contraindicated in stable COPD.

**Respiratory stimulants.** Not recommended for regular use.

**Non-pharmacologic treatment** includes rehabilitation, oxygen therapy, and surgical interventions.

Rehabilitation programs should include, at a minimum:

- Exercise training
- Education
- Nutrition counseling
Patients at all stages of disease benefit from exercise training programs, with improvements in exercise tolerance and symptoms of dyspnea and fatigue. Benefits can be sustained even after a single pulmonary rehabilitation program, whether it is conducted in an inpatient, outpatient, or home setting. The minimum length of an effective rehabilitation program is two months; the longer the program continues the more effective the results.

**Oxygen therapy.** The long-term administration of oxygen (>15 hours per day) to patients with chronic respiratory failure increases survival and has a beneficial impact on pulmonary arterial pressure, polycythemia (hematocrit > 55%), exercise capacity, lung mechanics, and mental state.

**Surgical treatments.** Bullectomy and lung transplantation may be considered in carefully selected patients with Stage IV: Very Severe COPD. There is currently no sufficient evidence that would support the widespread use of lung volume reduction surgery (LVRS).

There is no convincing evidence that mechanical ventilatory support has a role in the routine management of stable COPD.

**Component 4: Manage exacerbations**

COPD is often associated with exacerbations of symptoms. Many exacerbations are caused by infection of the tracheobronchial tree or an increase in air pollution, but the cause of about one-third of severe exacerbations cannot be identified.

How to assess the severity of an exacerbation:

- Lung function tests (may be difficult for sick patients to perform):
- Chest X-ray: Chest radiographs (posterior/ anterior plus lateral) identify complications such as pneumonia and alternative diagnoses that can mimic the symptoms of an exacerbation.
- ECG: Aids in the diagnosis of right ventricular hypertrophy, arrhythmias, and ischemic episodes.
- Other laboratory tests:  
  - Sputum culture and antibiogram to identify infection if there is no response to initial antibiotic treatment.
  - Biochemical tests to detect electrolyte disturbances, diabetes, and poor nutrition.
Home Management

Bronchodilators. Increase the dose and/or frequency of current bronchodilator therapy. If not already in use, add anticholinergics until symptoms improve.

Glucocorticosteroids. If baseline FEV$_1$ < 50% predicted, add 40 mg oral prednisolone per day for 10 days to the bronchodilator regimen. Nebulized abudesonide may be an alternative to oral glucocorticosteroids in the treatment of nonacidotic exacerbations.

Antibiotics. When symptoms of breathlessness and cough are increased and sputum is purulent and increased in volume, provide antibiotic coverage of the major bacterial pathogens involved in exacerbations, taking into account local patterns of antibiotic activity.

Hospital Management

Patients with the characteristics listed in Figure 2 below should be hospitalized. Indications for referral and the management of exacerbations of COPD in the hospital depend on local resources and the facilities of the local hospital.

![Figure 2: Indications](image)

<table>
<thead>
<tr>
<th>INDICATIONS FOR HOSPITAL ADMISSION FOR EXACERBATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marked increase in intensity of symptoms, such as sudden development of resting dyspnea</td>
</tr>
<tr>
<td>Severe background COPD</td>
</tr>
<tr>
<td>Onset of new physical signs (e.g., cyanosis, peripheral edema)</td>
</tr>
<tr>
<td>Failure of exacerbation to respond to initial medical management</td>
</tr>
<tr>
<td>Significant comorbidities</td>
</tr>
<tr>
<td>Newly occurring arrhythmias</td>
</tr>
<tr>
<td>Diagnostic uncertainty</td>
</tr>
<tr>
<td>Older age</td>
</tr>
<tr>
<td>Insufficient home support</td>
</tr>
</tbody>
</table>

Home Care or Hospital Care for End-Stage COPD Patients?

The risk of dying from an exacerbation of COPD is closely related to the development of respiratory acidosis, the presence of serious comorbidities, and the need for ventilatory support. Patients lacking these features are not at high risk of dying, but those with severe underlying COPD often require hospitalization in any case. Attempts at managing such patients entirely in the community have met with limited success, but returning them to their homes with increased social support and a supervised medical care program after an initial emergency room assessment has been much more successful. However, detailed cost-benefit analyses of these approaches have not been reported.
Introduction

Clinical trials have shown benefit in adjusted-dose warfarin (Coumadin) therapy in the treatment of atrial fibrillation. Meta-analysis and subset analysis have further defined the patients who can benefit the most from anticoagulation therapy. For the total population, anticoagulation therapy reduces the relative risk of stroke by 62%. For primary prevention, the absolute risk reduction for all strokes was 2.7% per year and numbers needed to treat was 37. For secondary prevention, it was 8.4% and 12, respectively. Although intracranial bleeding increased in patients receiving anticoagulation therapy, the increased incidence did not reach statistical significance.

Aspirin therapy is effective in reducing strokes in patients with atrial fibrillation, but the relative risk reduction is in the range of 22% with no significant reduction in overall mortality. Aspirin therapy is superior to placebo, but clearly not as effective as full anticoagulation therapy. Currently, there is insufficient data to support the newer antiplatelet agents as any more effective than aspirin in preventing embolic strokes.

The benefits for anticoagulation are not equal for all patients with atrial fibrillation. Older patients and those with significant heart disease have the highest risk for strokes and have the greatest benefit from anticoagulation therapy. Warfarin anticoagulation therapy is not clearly indicated for all patients with atrial fibrillation. Various factors require consideration in recommending that a patient receive anticoagulation therapy. In addition to the strict medical criteria, issues of adherence to therapy, lifestyle, philosophy and personal preference may play a role in the decision to initiate therapy.

Assessment

Patients considering therapy should have a comprehensive history examination with particular emphasis on the heart and cardiovascular system. Based on this information, the patient can be assigned to categories that stratify the risks and benefits of anticoagulation therapy. Patients with rheumatic heart disease and valve replacement almost universally need anticoagulation therapy. Patients who are over age 75 or who have significant heart disease are in a high-risk group. Patients under 60 with normal or near-normal cardiac function have low risk. Patients with more than one risk factor or who are over 60 have significant risk. The decision to treat them or not needs to be weighed against the potential risks.

Risks of care

Research studies enroll very select populations based on a willingness to receive treatment and adhere to the research protocol. Treatment of atrial fibrillation in a general population requires careful evaluation of the risks of care beyond the medi-
Atrial Fibrillation
Antithrombotic Treatment of Chronic Atrial Fibrillation

Shared decision making
Although the benefits of anticoagulation therapy are clearly established, all patients should understand and be actively involved in their anticoagulation therapy. Once the physician has interpreted the data from the patient’s history, physical examination, and diagnostic testing, he or she and the patient should jointly review the findings and come to a decision regarding anticoagulation therapy.

Clinical management and therapeutic goals
The physician should set a goal of maintaining the patient’s international normalized ratio (INR) between 2 and 3. During the initiation and adjustment period of therapy, the patient should be monitored frequently to avoid critically high INRs. Once the patient is in the therapeutic range, the patient should be monitored approximately once per month to avoid undetected fluctuations in the prothrombin time. The patient should receive education related to the appropriate use of warfarin, including information about the wide number of drug interactions. Patients should initially be told and subsequently reminded to avoid high-risk activities while on anticoagulation therapy, because such high-risk activity may potentially result in trauma.

Table 1: 2001 ACCP Consensus Conference Summary Recommendations for inpatients considered for long-term oral anticoagulation

<table>
<thead>
<tr>
<th>AGE</th>
<th>GENERIC NAME</th>
<th>BRAND NAME</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;60</td>
<td>Absent</td>
<td>ASA</td>
</tr>
<tr>
<td></td>
<td>Present</td>
<td>Warfarin</td>
</tr>
<tr>
<td></td>
<td></td>
<td>target INR 2.5 (range 2.0-3.0)</td>
</tr>
<tr>
<td>60-75 years</td>
<td>Absent</td>
<td>ASA</td>
</tr>
<tr>
<td></td>
<td>Present</td>
<td>Warfarin</td>
</tr>
<tr>
<td></td>
<td></td>
<td>target INR 2.5 (range 2.0-3.0)</td>
</tr>
<tr>
<td>&lt;75 years</td>
<td>All patients</td>
<td>Warfarin</td>
</tr>
<tr>
<td></td>
<td></td>
<td>target INR 2.5 (range 2.0-3.0)</td>
</tr>
</tbody>
</table>

*Risk factors for thromboembolism include HF, LVEF < 35%, and history of hypertension.
Patient with Chronic Atrial Fibrillation

History and physical exam
(Risk stratification)

Evaluation of Left Ventricular Function: History of CHF, hypertension, cardiomyopathy, ischemic heart disease

Valvular heart disease: History of rheumatic heart disease, congenital heart disease, acquired valvular disease

Previous events or comorbidity: History of CVA, TIA, embolic disease, diabetes

Anticoagulation risk: History of hemorrhagic stroke, gastrointestinal bleeding, bleeding diathesis, risk of significant trauma or injury, alcohol use, other medications, medical noncompliance

Diagnostic tests
(Within a year of starting therapy)

- Echocardiogram
- EKG
- CXR

Risk stratification

High risk
- Age: Greater than 75 years
- LV Dysfunction: EF < 40%
- History of CHF, stroke, TIA, embolic disease or HBP
- Non-rheumatic significant valvular disease

Intermediate risk
- (with one or no risk factors)
- Age: 60 to 75 years
- History of diabetes, coronary artery disease
- Thyrotoxicosis

Low risk
- Age: Less than 60 years
- Normal LVF
- Non-significant valvular abnormality

(see Aspirin therapy, below)

Rheumatic valvular disease and valve replacement

Contraindications for anticoagulation
History of GI bleeding, hemorrhagic stroke, bleeding diathesis, high risk for trauma or fall, alcohol abuse, high compliance risk

Risk/benefit assessment and decision

- Anticoagulation recommended in all patients
- Provider and patient make shared decision for anticoagulation

Aspirin therapy
If not contraindicated, requires close medical follow-up for TIA or other changes in status. May consider other anti-platelet agents.

Anticoagulation
(See anticoagulation monitoring decision tree, next page).
Anticoagulation Initiation and Monitoring Algorithm

Patient with chronic atrial fibrillation initiating anticoagulation therapy

Patient education
- Effects of alcohol
- Drug interactions
- Importance of regular monitoring
- Avoidance of activities that might result in significant trauma
- Foods rich in Vitamin K may affect INR

Initiate warfarin therapy
- Recommend initially 2.5-5 mg qd for 3 days
- Adjust down for the elderly and patients with hepatic insufficiency

3rd day protime
INR: 2-3

Prolonged
Non-therapeutic

Yes

Adjust therapy
Repeat protime at 5-7 days, 2 weeks, 3 weeks, 4 weeks

Adjust therapy
Repeat protimes
INR: 2-3

Prolonged
Non-therapeutic

Maintenance
4-6 weeks protimes

Prolonged
Non-therapeutic

Therapeutic goal
INR between 2-3

Atrial Fibrillation
Introduction

The initial guidelines for Primary Prevention of Cardiovascular Diseases were published in 1997 as an aid to health care professionals for treating patients without established coronary artery disease or other atherosclerotic diseases. They were intended to provide a comprehensive approach to treatment for patients across a wide spectrum of risk. The imperative to prevent the first episode of coronary disease or stroke or the development of aortic aneurysm and peripheral arterial disease remains as strong as ever because of the still-high rate of first events that are fatal or disabling or require expensive intensive medical care. There is growing evidence that most cardiovascular disease is preventable.

This 2002 update of the guideline acknowledges a number of advances in the field of primary prevention. It also integrates other guidelines and consensus statements developed since the initial guideline’s approval.

This guideline might be viewed as the entry point to the more specific and detailed recommendations and the rationale behind them. The recommendations, as presented in the accompanying tables, are therefore consistent with the recommendations listed in Tables 1 & 2.

The aspirin guidelines recommended here agree with the Task Force Report in the use of aspirin in persons at high coronary and stroke risk but use a ≥10% risk per 10 years rather than >6% risk over 10 years. This improves the likelihood of a positive balance of coronary risk reduction over bleeding and hemorrhagic stroke caused by aspirin.

Goals/Desired Outcomes

This guideline is intended to:

- Assist primary care providers in their assessment, management, and follow-up of patients who may be at risk for, but who have not yet manifested cardiovascular disease.
- Emphasize that adoption of healthy life habits is the cornerstone of primary prevention, including the avoidance of tobacco (including second hand smoke), healthy dietary patterns, weight control, and regular, appropriate exercise.
- Stress the important role of health care providers in supporting and reinforcing these public health recommendation for all patients.
Table 1: Guideline Recommendation Sources

- Agency for Healthcare Policy and Research Guidelines on Treating Tobacco Use and Dependence.
- AHA Dietary Guidelines, Revision 2000, the AHA Statement on Alcohol and Heart Disease.
- American Heart Association Scientific Statements and Advisories on Physical Activity and The American College of Sports Medicine Guidelines
- Clinical Guidelines for the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults from the National Heart, Lung, and Blood Institute Expert Panel and an accompanying statement from the AHA Nutrition Committee.
- American Diabetes Association Standards of Medical Care for Patients with Diabetes and the AHA Statement on Diabetes and Cardiovascular Disease.
- AHA Guidelines on The Primary Prevention of Stroke.

Table 2: Guide to Primary Prevention of Cardiovascular Disease and Stroke: Risk Assessment

<table>
<thead>
<tr>
<th>Risk Assessment</th>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk factor screening</td>
<td>Risk factor assessment in adults should begin at age 20 y. Family history of CHD should be regularly updated. Smoking status, diet, alcohol intake, and physical activity should be assessed at every routine evaluation. Blood pressure, body mass index, waist circumference, and pulse (to screen for atrial fibrillation) should be recorded at each visit (at least every 2 y). Fasting serum lipoprotein profile (or total and HDL cholesterol if fasting is unavailable) and fasting blood glucose should be measured according to patient’s risk for hyperlipidemia* and diabetes, respectively (at least every 5 y; if risk factors are present, every 2 y).</td>
</tr>
<tr>
<td>Global risk estimation</td>
<td>Every 5 y (or more frequently if risk factors change), adults, especially those 40 y of age or those with 2 risk factors, should have their 10-y risk of CHD assessed with a multiple risk score. Risk factors used in global risk assessment include age, sex, smoking status, systolic (and sometimes diastolic) blood pressure, total (and sometimes LDL) cholesterol, HDL cholesterol, 12, 28 and in some risk scores, diabetes 29, 30. Persons with diabetes or 10-y risk 20% can be considered at a level of risk similar to a patient with established cardiovascular disease (CHD risk equivalent). Equations for calculation of 10-y stroke risk are also available.</td>
</tr>
</tbody>
</table>

* U.S. Preventive Tasks Force recommends cholesterol screening for all men 35-65 and women 45-65
Diagnosis

Table 2 identifies risk assessments and recommendations for the primary prevention of cardiovascular disease and stroke. The assessment of absolute cardiac risk is increasingly advocated by international organizations and by individual risk factor guidelines in the United States. The Framingham database has been widely used, though HMSA acknowledges that the multiple risk score may not apply equally to all sexes, races, and ethnic groups. The use of more sophisticated technologies than a risk factor inventory and global risk score has been addressed, and we conclude that most screening tests for occult atherosclerosis remain in the research arena, with the exception of the ankle-brachial blood pressure index.

Risk reduction

Interventions to reduce risks must be based on a decision made by the patient with the support of the physician. Many or most asymptomatic patients will not benefit from the treatment, but the population at risk must be treated for some to realize benefits. Patients need to be informed of both the risks and potential benefits of treatment to make an informed decision.

Multiple therapies

Physicians must work with the patient to develop an acceptable care plan that maximizes the potential benefits. Multiple risk factor interventions should be tailored to the individual.

The recommended interventions involving “nutriceutical” and pharmaceutical interventions in Table 3 (next page) have support from randomized clinical trials establishing their efficacy and safety. Dietary supplements, and potentially cardioprotective drugs other than aspirin require additional investigation in well-designed clinical trials in persons without established cardiovascular disease.
TABLE 3. Guide to Primary Prevention of Cardiovascular Disease and Stroke: Risk Intervention

<table>
<thead>
<tr>
<th>Risk Intervention and Goals</th>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Smoking</strong></td>
<td>Ask about tobacco use status at every visit. In a clear, strong, and personalized manner, advise every tobacco user to quit. Assess the tobacco user’s willingness to quit. Assist by counseling and developing a plan for quitting. Arrange follow-up referral to special programs, or pharmacotherapy. Urge avoidance of exposure to secondhand smoke at work or home.</td>
</tr>
<tr>
<td><strong>BP control</strong></td>
<td>Promote healthy lifestyle modification. Advise weight reduction; reduction of sodium intake; consumption of fruits, vegetables, and low-fat dairy products; moderation of alcohol intake; and physical activity in persons with BP of ≥130 mm Hg systolic or 80 mm Hg diastolic. For persons with renal insufficiency or heart failure, initiate drug therapy if BP is ≥130 mm Hg systolic or 85 mm Hg diastolic (≥80 mm Hg diastolic for patients with diabetes). Initiate drug therapy for those with BP ≥140/90 mm Hg if 6 to 12 months of lifestyle modification is not effective, depending on the number of risk factors present. Add BP medications, individualized to other patient requirements and characteristics (eg, age, race, need for drugs with specific benefits).</td>
</tr>
<tr>
<td><strong>Dietary intake</strong></td>
<td>Advise consumption of a variety of fruits, vegetables, grains, low-fat or nonfat dairy products, fish, legumes, poultry, and lean meats. Match energy intake with energy needs and make appropriate changes to achieve weight loss when indicated. Modify food choices to reduce saturated fats (&lt;10% of calories), cholesterol (&lt;300 mg/dL), and trans-fatty acids by substituting grains and unsaturated fatty acids from fish, vegetables, legumes, and nuts. Limit salt intake to &lt;6 g/d. Limit alcohol intake (&lt;2 drinks/d in men, &lt;1 drink/d in women) among those who drink.</td>
</tr>
<tr>
<td><strong>Aspirin</strong></td>
<td>Do not recommend for patients with aspirin intolerance. Low-dose aspirin increases risk for gastrointestinal bleeding and hemorrhagic stroke. Do not use in persons at increased risk for these diseases. Benefits of cardiovascular risk reduction outweigh these risks in most patients at higher coronary risk. Doses of 75–160 mg/d are as effective as higher doses. Therefore, consider 75–160 mg aspirin per day for persons at higher risk (especially those with 10-y risk of CHD &gt;10%).</td>
</tr>
<tr>
<td><strong>Blood lipid management</strong></td>
<td>If LDL-C is above goal range, initiate additional therapeutic lifestyle changes consisting of dietary modifications to lower LDL-C. &lt;7% of calories from saturated fat, cholesterol &lt;200 mg/dL, and, if further LDL-C lowering is required, dietary options (plant stanoles/sterols not to exceed 2 g/dL and/or increased viscous [soluble] fiber [10–25 g/dL]), and additional emphasis on weight reduction and physical activity. If LDL-C is above goal range, rule out secondary causes (liver function test, thyroid-stimulating hormone level, urinalysis). After 12 weeks of therapeutic lifestyle change, consider LDL-lowering drug therapy if ≥2 risk factors are present, 10-y risk is &gt;10%, and LDL-C is ≥130 mg/dL; ≥2 risk factors are present, 10-y risk is &lt;10%, and LDL-C is ≥160 mg/dL; or ≤1 risk factor is present and LDL-C is ≥190 mg/dL. Start drugs and advance dose to bring LDL-C to goal range, usually a statin but also consider bile acid–binding or niacin. If LDL-C goal not achieved, consider combination therapy (statin + resin, statin + niacin). After LDL-C goal has been reached, consider triglyceride level: If 150–199 mg/dL, treat with therapeutic lifestyle changes. If 200–499 mg/dL, treat elevated non-HDL-C with therapeutic lifestyle changes and, if necessary, consider higher doses of statin or adding niacin or fibrate. If &gt;500 mg/dL, treat with fibrate or niacin to reduce risk of pancreatitis. If HDL-C is &lt;40 mg/dL in men and &lt;50 mg/dL in women, initiate or intensify therapeutic lifestyle changes. For higher-risk patients, consider drugs that raise HDL-C (eg, niacin, fibrates, statins).</td>
</tr>
<tr>
<td><strong>Physical activity</strong></td>
<td>If cardiovascular, respiratory, metabolic, orthopedic, or neurological disorders are suspected, or if patient is middle-aged or older and is sedentary, consult physician before initiating vigorous exercise program. Moderate-intensity activities (40% to 60% of maximum capacity) are equivalent to a brisk walk (15–20 min per mile). Additional benefits are gained from vigorous-intensity activity (&gt;60% of maximum capacity) for 20–40 min on 3–5 d/wk. Recommend resistance training with 8–10 different exercises, 1–2 sets per exercise, and 10–15 repetitions at moderate intensity ≥2 d/wk. Flexibility training and an increase in daily lifestyle activities should complement this regimen.</td>
</tr>
<tr>
<td><strong>Weight management</strong></td>
<td>Initiate weight-management program through caloric restriction and increased caloric expenditure as appropriate. For overweight/obese persons, reduce body weight by 10% in first year of therapy.</td>
</tr>
<tr>
<td><strong>Diabetes management</strong></td>
<td>Initiate appropriate hypoglycemic therapy to achieve near-normal fasting plasma glucose or as indicated by near-normal HbA1c. First step is diet and exercise. Second-step therapy is usually oral hypoglycemic drugs: sulfonylureas and/or metformin with ancillary use of acarbose and thiazolidinediones. Third-step therapy is insulin. Treat other risk factors more aggressively (eg, change BP goal to &lt;130/80 mm Hg and LDL-C goal to &lt;100 mg/dL).</td>
</tr>
<tr>
<td><strong>Chronic atrial fibrillation</strong></td>
<td>Irregular pulse should be verified by an electrocardiogram. Conversion of appropriate individuals to normal sinus rhythm. For patients in chronic or intermittent atrial fibrillation, use warfarin anticoagulants to INR 2.0–3.0 (target 2.5). Aspirin (325 mg/d) can be used as an alternative in those with certain contraindications to oral anticoagulation. Patients &lt;65 y of age without high risk may be treated with aspirin.</td>
</tr>
</tbody>
</table>

BP indicates blood pressure; CHD, coronary heart disease; LDL-C, low-density lipoprotein cholesterol; HDL-C, high-density lipoprotein cholesterol; and INR, international normalized ratio.
Cardiovascular Disease and Stroke
Primary Prevention Algorithm

History with risk factor analysis

Documented coronary artery disease

Risk stratification for treatment options:
Intervention strongly recommended

Risk stratification
Modifiable risks: cholesterol, smoking, hypertension, diabetes, obesity

Go to
Lifestyle changes appropriate for all patients
(next page)

Multiple risk factor intervention:
Goals
Cholesterol: LDL < 100 mg/dL
HDL > 40mg/dL
BP: below 140/90
HbA₁c below 7%
Smoking cessation
Other Rx
ASA
Post MI: Beta-blockers, ACE inhibitors
Cardiovascular Disease and Stroke
Primary Prevention Algorithm

Lifestyle changes appropriate for all patients
Encourage exercise (potential to increase HDL)
Males: consider ASA daily
Postmenopausal females: HRT (possible benefit)
Obesity: weight reduction

Obesity

Obesity management
Nutritional counseling; encourage exercise

Cholesterol

Fasting lipoprotein stratification
LDL < 130 mg/dL: education and 5-year lipid profile
LDL 130 - 159 mg/dL: borderline – individual decision
LDL ≥ 160 mg/dL: high risk – strongly encourage risk factor intervention
HDL < 40 mg/dL: higher risk – may improve with exercise or by stopping smoking for smokers

Smoking

Smoking cessation
Counseling with every physician visit; referral to smoking cessation program

Hypertension

Hypertension intervention
Goal: blood pressure below 140/90
BP > 140/90 < 150/100: lifestyle intervention/medication for persistent HBP
BP > 150/100 < 160/110: lifestyle intervention and medication
BP > 160/110: lifestyle and aggressive medical intervention; consider evaluation for etiology

Diabetes

Diabetes management
Goal: HbA1c < 7%
BP: <130/85 mg/dL
Cholesterol: LDL > 130 mg/dL drug therapy
LDL goal < 100 mg/dL

Lifestyle changes appropriate for all patients
Encourage exercise (potential to increase HDL)
Males: consider ASA daily
Postmenopausal females: HRT (possible benefit)
Obesity: weight reduction

Obesity

Obesity management
Nutritional counseling; encourage exercise

Cholesterol

Fasting lipoprotein stratification
LDL < 130 mg/dL: education and 5-year lipid profile
LDL 130 - 159 mg/dL: borderline – individual decision
LDL ≥ 160 mg/dL: high risk – strongly encourage risk factor intervention
HDL < 40 mg/dL: higher risk – may improve with exercise or by stopping smoking for smokers

Smoking

Smoking cessation
Counseling with every physician visit; referral to smoking cessation program

Hypertension

Hypertension intervention
Goal: blood pressure below 140/90
BP > 140/90 < 150/100: lifestyle intervention/medication for persistent HBP
BP > 150/100 < 160/110: lifestyle intervention and medication
BP > 160/110: lifestyle and aggressive medical intervention; consider evaluation for etiology

Diabetes

Diabetes management
Goal: HbA1c < 7%
BP: <130/85 mg/dL
Cholesterol: LDL > 130 mg/dL drug therapy
LDL goal < 100 mg/dL
Introduction

Elevated blood cholesterol is a major modifiable risk factor of coronary artery disease (CAD). As the leading cause of death in the U.S., CAD is responsible for over 490,000 deaths per year. This represents a considerable medical expense as well as significant lost productivity. The United States Preventive Services Task Force (USPSTF) recommends screening for high blood cholesterol in all men ages 35-65 and women ages 45-65.

This guideline is based on the Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). The ATP III builds on previous ATP reports and expands the indications for intensive cholesterol-lowering therapy in clinical practice. Please note that these guidelines are intended to aid, not replace, the physician's clinical judgment, which must ultimately determine the appropriate care for each individual.

Goals/Desired Outcomes

This aim of this guideline is to establish criteria for improving cholesterol management. Clinical guidelines related to cholesterol must be discussed in the context of total cardiovascular risk reduction. The physician’s cholesterol risk assessment and recommended treatment must consider the advantages of multiple interventions that could potentially benefit the patient.

Treatment

Research from experimental animals, laboratory investigations, epidemiology, and genetic forms of hypercholesterolemia indicates that elevated LDL cholesterol is a major cause of CHD. In addition, recent clinical trials robustly show that LDL-lowering therapy reduces risk for CHD. For these reasons, ATP III (next page) continues to identify elevated LDL cholesterol as the primary target of cholesterol-lowering therapy. As a result, the primary goals of therapy and the cutpoints for initiating treatment are stated in terms of LDL.

Note: See diagnosis and treatment step algorithm on following pages.
Focus on multiple risk factors

- Raises persons with diabetes without Coronary Heart Disease (CHD), most of whom display multiple risk factors, to the risk level of CHD risk equivalent.
- Uses Framingham projections of 10-year absolute CHD risk (i.e., the percent probability of having a CHD event in 10 years) to identify certain patients with multiple (2+) risk factors for more intensive treatment.
- Identifies persons with multiple metabolic risk factors (metabolic syndrome) as candidates for intensified therapeutic lifestyle changes.

Modifications of lipid and lipoprotein classification

- Identifies LDL cholesterol <100 mg/dL as optimal.
- Raises categorical low HDL cholesterol from <35 mg/dL to <40 mg/dL because the latter is a better measure of a depressed HDL.
- Lowers the triglyceride classification cutpoints to give more attention to moderate elevations.

Support for Implementation

- Recommends a complete lipoprotein profile (total cholesterol, LDL cholesterol, HDL cholesterol, and triglycerides) as the preferred initial test, rather than screening for total cholesterol and HDL alone.
- Encourages use of plant stanols/sterols and viscous (soluble) fiber as therapeutic dietary options to enhance lowering of LDL cholesterol.
- Presents strategies for promoting adherence to therapeutic lifestyle changes and drug therapies.
- Recommends treatment beyond LDL lowering for persons with triglycerides ≤200 mg/dL.
Step 1
Determine lipoprotein levels—obtain complete lipoprotein profile after 9- to 12-hour fast.

ATP III Classification of LDL, Total, and HDL Cholesterol (mg/dL)

<table>
<thead>
<tr>
<th>LDL Cholesterol - Primary Target of Therapy</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;100</td>
<td>Optimal</td>
</tr>
<tr>
<td>100-129</td>
<td>Near optimal/above optimal</td>
</tr>
<tr>
<td>130-159</td>
<td>Borderline high</td>
</tr>
<tr>
<td>160-189</td>
<td>High</td>
</tr>
<tr>
<td>&gt;190</td>
<td>Very high</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total Cholesterol</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;200</td>
<td>Desirable</td>
</tr>
<tr>
<td>200-239</td>
<td>Borderline high</td>
</tr>
<tr>
<td>&gt;240</td>
<td>High</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HDL Cholesterol</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;40</td>
<td>Low</td>
</tr>
<tr>
<td>≥60</td>
<td>High</td>
</tr>
</tbody>
</table>

Step 2
Identify presence of clinical atherosclerotic disease that confers high risk for coronary heart disease (CHD) events (CHD risk equivalent):

- Clinical CHD
- Symptomatic carotid artery disease
- Peripheral arterial disease
- Abdominal aortic aneurysm

Step 3
Determine presence of major risk factors (other than LDL):

**Major Risk Factors (Exclusive of LDL Cholesterol) That Modify LDL Goals**

- Cigarette smoking
- Hypertension (BP ≥140/90 mmHg or on antihypertensive medication)
- Low HDL cholesterol (<40 mg/dL)*
- Family history of premature CHD (CHD in male first degree relative <55 years; CHD in female first degree relative <65 years)
- Age (men ≥45 years; women ≥55 years)

* HDL cholesterol ≥60 mg/dL counts as a “negative” risk factor; its presence removes one risk factor from the total count.

Note: in ATP III, diabetes is regarded as CHD risk equivalent.
Step 4
If 2+ risk factors (other than LDL) are present without CHD or CHD risk equivalent, assess 10-year (short-term) CHD risk (see Framingham tables).

Three levels of 10-year risk:
- >20% — CHD risk equivalent
- 10-20%
- <10%

Step 5
Determine risk category:
- Establish LDL goal of therapy
- Determine need for therapeutic lifestyle changes (TLC)
- Determine level for drug consideration

LDL Cholesterol Goals and Cutpoints for Therapeutic Lifestyle Changes (TLC) and Drug Therapy in Different Risk Categories.

<table>
<thead>
<tr>
<th>Risk Category</th>
<th>LDL Goal</th>
<th>LDL Level at Which to Initiate Therapeutic Lifestyle Changes (TLC)</th>
<th>LDL Level at Which to Consider Drug Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHD or CHD Risk Equivalents</td>
<td>&lt;100 mg/dL</td>
<td>&gt;100 mg/dL</td>
<td>&gt;130 mg/dL (100-129 mg/dL: drug optional)*</td>
</tr>
<tr>
<td>(10-year risk &gt;20%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2+ Risk Factors</td>
<td>&lt;130 mg/dL</td>
<td>&gt;130 mg/dL</td>
<td>10-year risk 10-20%: ≥130 mg/dL</td>
</tr>
<tr>
<td>(10-year risk ≤20%)</td>
<td></td>
<td></td>
<td>10-year risk &lt;10%: ≥160 mg/dL</td>
</tr>
<tr>
<td>0-1 Risk Factor†</td>
<td>&lt;160 mg/dL</td>
<td>≥160 mg/dL</td>
<td>≥190 mg/dL (160-189 mg/dL: LDL-lowering drug optional)</td>
</tr>
</tbody>
</table>

* Some authorities recommend use of LDL-lowering drugs in this category if an LDL cholesterol <100 mg/dL cannot be achieved by therapeutic lifestyle changes. Others prefer use of drugs that primarily modify triglycerides and HDL, e.g., nicotinic acid or fibrate. Clinical judgment also may call for deferring drug therapy in this subcategory.
† Almost all people with 0-1 risk factor have a 10-year risk <10%, thus 10-year risk assessment in people with 0-1 risk factor is not necessary.

Step 6
Initiate therapeutic lifestyle changes (TLC) if LDL is above goal.

TLC Features
- TLC Diet:
  - Saturated fat <7% of calories, cholesterol <200 mg/day
  - Consider increased viscous (soluble) fiber (10-25 g/day) and plant stanols/sterols (2g/day) as therapeutic options to enhance LDL lowering
- Weight management
- Increased physical activity.
**Step 7**

Consider adding drug therapy if LDL exceeds levels shown in Step 5 table:

- Consider drug simultaneously with TLC for CHD equivalents.
- Consider adding drug to TLC after 3 months for other risk categories.

**Drugs affecting Lipoprotein Metabolism**

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Agents and Daily Doses</th>
<th>Lipid/Lipoprotein Effects</th>
<th>Side Effects</th>
<th>Contraindications</th>
</tr>
</thead>
</table>
| HMG CoA reductase inhibitors (statins) | Lovastin (20-80 mg) | LDL ↓ 18-55% | Myopathy | Absolute:  
  - Active or chronic liver disease  
  Relative:  
  - Concomitant use of certain drugs |
| | Pravastatin (20-40 mg) | HDL ↑ 5-15% | Increased liver enzymes |
| | Simvastatin (20-80 mg) | TG ↓ 7-30% |
| | Fluvastatin (20-80 mg) |
| | Atorvastatin (10-80 mg) |
| Bile acid sequestrants | Cholestyramine (4-16 g) (SELECT only) | LDL ↓ 15-30% | Gastrointestinal distress | Absolute:  
  - Dysbetalipoproteinemia  
  TG>400 mg/dL |
| | Colestipol (5-20 g) (QUEST granular only) | HDL ↑ 3-5% | Constipation | Relative:  
  - TG>200 mg/dL |
| | | TG ↓ No change or increase | Decreased absorption of other drugs |
| Nicotinic acid | Immediate release (1.5-3 g) | LDL ↓ 5-25% | Flushing | Absolute:  
  - Chronic liver disease  
  - Severe gout  
  Relative:  
  - Diabetes  
  - Hyperuricemia  
  - Peptic ulcer disease |
| | Extended release (Niaspan) (1-2 g) | HDL ↑ 15-35% | Hyperglycemia  
  Hyperuricemia (or gout) | |
| | Controlled release (1-2 g) | TG ↓ 20-50% | Upper GI distress  
  Hepatotoxicity |
| Fibric acids | Gemfibrozil (600 mg BID) | LDL ↓ 5-20% | Dypiesia  
  Gallstones  
  Myopathy | Absolute:  
  - Severe renal disease  
  - Severe hepatic disease |
| | Fenofibrate (200 mg) | (may be increased in patients with high TG) | HDL ↑ 10-20% |
| | Clofibrate (1000 mg BID) | TG ↓ 20-50% |

1 Cyclosporine, macrolide, various anti-fungal agents, and cytochrome P-450 inhibitors (fibrates and niacin should be used with appropriate caution).
Step 8
Identify metabolic syndrome and treat, if present, after 3 months of TLC.

Clinical Identification of the Metabolic Syndrome - Any 3 of the Following:

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Defining Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal obesity*</td>
<td>Waist circumference†</td>
</tr>
<tr>
<td>Men</td>
<td>&gt;102 cm (&gt;40 in)</td>
</tr>
<tr>
<td>Women</td>
<td>&gt;88 cm (&gt;35 in)</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>≥150 mg/dL</td>
</tr>
<tr>
<td>HDL cholesterol</td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>&lt;40 mg/dL</td>
</tr>
<tr>
<td>Women</td>
<td>&lt;50 mg/dL</td>
</tr>
<tr>
<td>Blood pressure</td>
<td>≥130/≥85 mmHg</td>
</tr>
<tr>
<td>Fasting glucose</td>
<td>≥110 mg/dL</td>
</tr>
</tbody>
</table>

* Overweight and obesity are associated with insulin resistance and the metabolic syndrome. However, the presence of abdominal obesity is more highly correlated with the metabolic risk factors than is an elevated body mass index (BMI). Therefore, the simple measure of waist circumference is recommended to identify the body weight component of the metabolic syndrome.

† Some male patients can develop multiple metabolic risk factors when the waist circumference is only marginally increased, e.g., 94-102 cm (37-39 in). Such patients may have a strong genetic contribution to insulin resistance. They should benefit from changes in life habits, similarly to men with categorical increases in waist circumference.

Treatment of the metabolic syndrome

- Treat underlying causes (overweight/obesity and physical inactivity):
  - Intensify weight management
  - Increase physical activity

- Treat lipid and non-lipid risk factors if they persist despite these lifestyle therapies:
  - Treat hypertension
  - Use aspirin for CHD patients to reduce prothrombotic state
  - Treat elevated triglycerides and/or low HDL (as shown in Step 9)
Step 9

Treat elevated triglycerides.

ATP III Classification of Serum Triglycerides (mg/dL)

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;150</td>
<td>Normal</td>
</tr>
<tr>
<td>150-199</td>
<td>Borderline high</td>
</tr>
<tr>
<td>200-499</td>
<td>High</td>
</tr>
<tr>
<td>≥500</td>
<td>Very high</td>
</tr>
</tbody>
</table>

Treatment of elevated triglycerides (≥150 mg/dL)

- Primary aim of therapy is to reach LDL goal
- Intensify weight management
- Increase physical activity
- If triglycerides are ≥200 mg/dL after LDL goal is reached, set secondary goal for non-HDL cholesterol (total – HDL) 30 mg/dL higher than LDL goal.

Comparison of LDL Cholesterol and Non-HDL Cholesterol Goals for Three Risk Categories

<table>
<thead>
<tr>
<th>Risk Category</th>
<th>LDL Goal (mg/dL)</th>
<th>Non-HDL Goal (mg/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHD and CHD Risk Equivalent (10-year risk for CHD &gt;20%)</td>
<td>&lt;100</td>
<td>&lt;130</td>
</tr>
<tr>
<td>Multiple (2+) Risk Factors and 10-year risk ≤20%</td>
<td>&lt;130</td>
<td>&lt;160</td>
</tr>
<tr>
<td>0-1 Risk Factor</td>
<td>&lt;160</td>
<td>&lt;190</td>
</tr>
</tbody>
</table>

If triglycerides 200-499 mg/dL after LDL goal is reached, consider adding drug if needed to reach non-HDL goal:

- intensify therapy with LDL-lowering drug, or
- add nicotinic acid or fibrate to further lower VLDL.

If triglycerides ≥500 mg/dL, first lower triglycerides to prevent pancreatitis:

- very low-fat diet (<15% of calories from fat)
- weight management and physical activity
- fibrate or nicotinic acid
- when triglycerides <500 mg/dL, turn to LDL-lowering therapy

Treatment of low HDL cholesterol (<40 mg/dL)

- First reach LDL goal, then:
- Intensify weight management and increase physical activity
- If triglycerides 200-499 mg/dL, achieve non-HDL goal
- If triglycerides <200 mg/dL (isolated low HDL) in CHD or CHD equivalent consider nicotinic acid or fibrate
**Estimating 10-year risk for men and women (Step 4)**

Risk assessment for determining the 10-year risk for developing CHD is carried out using Framingham risk scoring (Table B1 for men and Table B2 for women). Risk factors include age, total cholesterol, HDL cholesterol, systolic blood pressure, treatment for hypertension, and cigarette smoking.

The first step is to calculate the number of points for each risk factor. For initial assessment, values for total cholesterol and HDL cholesterol are required. Framingham estimates are more robust for total cholesterol than for LDL cholesterol. Note, however, that the LDL cholesterol level remains the primary target of therapy. Total cholesterol and HDL cholesterol values should be the average of at least two measurements obtained from lipoprotein analysis. The blood pressure value used is that obtained at the time of assessment, regardless of whether the person is on antihypertensive therapy. However, if the person is on antihypertensive treatment, an extra point is added beyond points for the blood pressure reading because treated hypertension carries residual risk (see Tables B1 and B2). The average of several blood pressure measurements, as recommended by the Joint National Committee (JNC), is needed for an accurate measure of baseline blood pressure. (The designation “smoker” means any cigarette smoking in the past month). The total risk score sums the points for each risk factor. The 10-year risk for myocardial infarction and coronary death (hard CHD) is estimated from total points, and the person is categorized according to absolute 10-year risk as indicated above (see Table 5).
### Table B1

**Estimate of 10-Year Risk for Men**

(Framingham Point Scores)

<table>
<thead>
<tr>
<th>Age</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>20-34</td>
<td>-9</td>
</tr>
<tr>
<td>35-39</td>
<td>-4</td>
</tr>
<tr>
<td>40-44</td>
<td>0</td>
</tr>
<tr>
<td>45-49</td>
<td>3</td>
</tr>
<tr>
<td>50-54</td>
<td>6</td>
</tr>
<tr>
<td>55-59</td>
<td>8</td>
</tr>
<tr>
<td>60-64</td>
<td>10</td>
</tr>
<tr>
<td>65-69</td>
<td>11</td>
</tr>
<tr>
<td>70-74</td>
<td>12</td>
</tr>
<tr>
<td>75-79</td>
<td>13</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total Cholesterol Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age 20-39</td>
</tr>
<tr>
<td>&lt;160</td>
</tr>
<tr>
<td>160-199</td>
</tr>
<tr>
<td>200-239</td>
</tr>
<tr>
<td>240-279</td>
</tr>
<tr>
<td>≥280</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Points</th>
<th>Age 20-39</th>
<th>Age 40-49</th>
<th>Age 50-59</th>
<th>Age 60-69</th>
<th>Age 70-79</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nonsmoker</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Smoker</td>
<td>8</td>
<td>5</td>
<td>3</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HDL (mg/dL) Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥60</td>
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Introduction

In patients diagnosed with chronic heart failure (CHF), effective evaluation and treatment is critical to reduce mortality and increase quality of life. These guidelines describe accepted diagnostic and treatment strategies primary care physicians can use in managing CHF patients. The guidelines are based on those of the American College of Cardiology/American Heart Association and the Agency for Health Care Policy and Research (unless otherwise referenced), as well as recommendations and input from cardiologists and primary care physicians. These guidelines pertain only to systolic left ventricular dysfunction, the most common and most widely studied type of CHF.

Symptoms of heart failure

CHF is defined as a condition in which the heart, in the presence of adequate venous return, is unable to pump enough blood to meet the oxygen demands of the body. Any patient diagnosed with paroxysmal nocturnal dyspnea, dyspnea upon exertion, or orthopnea as well as other symptoms (such as decreased exercise tolerance, fatigue, chest pain, edema) should undergo evaluation for heart failure.

Etiology

Prior to initiating therapy, the cause of CHF should be established. Myocardial infarction, long-standing hypertension and ischemic heart disease are the most common causes of CHF.

Diagnosis and Initial Evaluation

The initial evaluation should include the following:

- Physical examination
- Patient history - including coronary artery disease (CAD), valvular heart disease, diabetes mellitus, hypertension, viral illness potentially associated with cardiopathy, anemia, and substance abuse (alcohol, cocaine, methamphetamine)
- Laboratory tests - including complete blood count, serum creatinine, serum albumin, serum electrolytes, liver function, urinalysis, electrocardiogram, blood urea nitrogen, and thyroid stimulating hormone (for patients 65 and older)
- Imaging tests - echocardiography is the first choice to determine ejection fraction. Multiple gated acquisition may be considered if echocardiography does not provide needed information.

Guideline Summary

- CHF is a condition in which the heart is unable to pump enough blood to meet $O_2$ demands of the body.
- The new approach to the classification of HF emphasizes both the evolution and progression of the disease.
- Stage A—Patients at high risk for developing HF because of the presence of conditions strongly associated with HF.
- Stage B—Patients who have developed structural heart disease strongly associated with the development of HF without symptoms.
- Stage C—Patients who have current or prior symptoms of HF associated with underlying structural heart disease.
- Stage D—Patients with advanced heart disease and marked symptoms of HF at rest despite maximal medical therapy and who require specialized interventions.
Stages of Heart Failure

The new approach to the classification of HF emphasizes both the evolution and the progression of the disease. Four stages of heart failure have been identified.

Stage A
Patients in Stage A are at high risk of developing HF because of the presence of conditions strongly associated with the development of HF. Such patients have no identified structural or functional abnormalities of the pericardium, myocardium, or cardiac valves and have never shown signs or symptoms of HF.

Examples: systemic hypertension; coronary artery disease; diabetes mellitus; history of cardiotoxic drug therapy or alcohol abuse; personal history of rheumatic fever; family history of cardiomyopathy.

Stage B
Patients in Stage B have developed structural heart disease that is strongly associated with the development of HF but who have never shown signs or symptoms of HF.

Examples: left ventricular hypertrophy or fibrosis; left ventricular dilation of hypocontractility; asymptomatic valvular heart disease; previous myocardial infarction.

Stage C
Patients in Stage C have current or prior symptoms of HF associated with underlying structural heart disease.

Examples: Dyspnea or fatigue due to left ventricular systolic dysfunction; asymptomatic patients who are undergoing treatment for prior symptoms of HF.

Stage D
Patients in Stage D have advanced structural heart disease and marked symptoms of HF at rest despite maximum medical therapy and require specialized interventions.

Examples: Patients who are frequently hospitalized for HF or cannot be safely discharged from the hospital; patients in the hospital awaiting heart transplantation; patients at home receiving continuous intravenous support for symptom relief or being supported with a mechanical circulatory assist device; patients in a hospice setting for the management of HF.

Treatment

Stage A

Patients at high risk of developing Left Ventricular Dysfunction HF

Class I Recommendations

- Control of systolic and diastolic hypertension in accordance with recommended guidelines
- Treatment of lipid disorders in accordance with recommended guidelines
• Avoidance of patient behaviors that may increase the risk of HF (e.g., smoking, alcohol consumption, and illicit drug use)
• Angiotensin converting enzyme (ACE) inhibition in patients with a history of atherosclerotic vascular disease, diabetes mellitus, or hypertension and associated cardiovascular risk factors.
• Control of ventricular rate in patients with supraventricular tachyarrhythmias
• Treatment of thyroid disorders
• Periodic evaluation for signs and symptoms of HF

Stage B
Patients with Left Ventricular Dysfunction who have not developed symptoms
Class I Recommendations
• ACE inhibition in patients with a recent or remote history of myocardial infarction regardless of ejection fraction
• ACE inhibition in patients with a reduced ejection fraction, whether or not they have experienced a myocardial infarction
• Beta-blockade in patients with a recent myocardial infarction regardless of ejection fraction
• Beta-blockade in patients with a reduced ejection fraction, whether or not they have experienced a myocardial infarction
• Valve replacement or repair for patients with hemodynamically significant valvular stenosis or regurgitation
• Regular evaluation for signs and symptoms of HF
• Measures listed as Class I recommendations for patients in Stage A.

Stage C
Patients with symptomatic Left Ventricular Dysfunction with current or prior symptoms
General Measures
Measures listed as Class 1 recommendations for patients in stages A and B are also appropriate for patients with current or prior symptoms of HF. Moderate sodium restriction is indicated, along with daily measurement of weight, to facilitate effective use of lower and safer doses of diuretic drugs. Immunization with influenza and pneumococcal vaccines may reduce the risk of respiratory infection. Although most patients should not participate in heavy labor or exhaustive sports, physical activity should be encouraged, except during periods of acute decompensation or in patients with suspected myocarditis. Restriction of activity contributes to physical deconditioning, which may adversely affect clinical status and contribute to the exercise intolerance of patients with HF.
Perhaps the most effective yet least utilized measure that should be pursued in patients with HF is close attention and follow-up. Noncompliance with diet and medications can dramatically affect the clinical status of patients. An increase in body weight and minor changes in symptoms commonly precede the major clinical episodes that require emergency care or hospitalization. Patient education and close supervision (which includes monitoring by the patient and family between physician visits) can reduce the chances of noncompliance, and can often lead to detection of changes early enough to give a health care provider the opportunity to initiate treatment that can help to avoid clinical deterioration and hospitalization. Supervision between physician visits may be performed by a nurse or physician assistant with special training in the care of patients with HF.

Recommendations for treatment of symptomatic Left Ventricular Systolic Dysfunction

Class I

- Diuretics in patients who have evidence of fluid retention.
- ACE inhibition in all patients, unless contraindicated.
- Beta-adrenergic blockade in all stable patients, unless contraindicated. Patients should have no or minimal evidence of fluid retention and should not have required treatment recently with an intravenous positive inotropic agent.
- Digitalis for the treatment of symptoms of HF, unless contraindicated.
- Withdrawal of drugs known to adversely affect the clinical status of patients (e.g., nonsteroidal anti-inflammatory drugs, most antiarrhythmic drugs, and most calcium channel blocking drugs).
- Measures listed as Class I recommendations for patients in stages A and B.

Class IIa

- Spironolactone in patients with recent or current Class IV symptoms, preserved renal function, and a normal potassium concentration.
- Exercise training as an adjunctive approach to improve clinical status in ambulatory patients.
- Angiotensin receptor blockade in patients who are being treated with digitalis, diuretics, and a beta-blocker and who cannot be given an ACE inhibitor because of cough or angioedema.
- A combination of hydralazine and a nitrate in patients who are being treated with digitalis, diuretics, and a beta-blocker and who cannot be given an ACE inhibitor because of hypotension or renal insufficiency.

Class IIb

- Addition of an angiotensin receptor blocker to an ACE inhibitor.
• Addition of a nitrate (alone or in combination) with hydralazine to an ACE inhibitor in patients who are also being given digitalis, diuretics, and a beta-blocker.

**Note:** All recommendations provided in this document follow the format of previous ACC/AHA guidelines:
- Class I: Conditions for which there is evidence and/or general agreement that a given procedure or treatment is useful and effective.
- Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of performing the procedure/therapy.
- Class IIa: Weight of evidence/opinion is in favor of usefulness/opinion.
- Class IIb: Usefulness/efficacy is less well established by evidence/opinion.

**Drugs Recommended for Routine Use** (see Table 2 at end of guideline)
Most patients with symptomatic left ventricular dysfunction should be routinely managed with a combination of four types of drugs: a diuretic, and ACE inhibitor, a beta-adrenergic blocker, and digitalis (usually). Patients with evidence of fluid retention should be given a diuretic until a euvolemic state is achieved, and diuretic therapy should be continued to prevent the recurrence of fluid retention. Even if the patient has responded favorably to the diuretic, treatment with an ACE inhibitor and a beta-blocker should be initiated and maintained in patients who can tolerate them since they have been shown to favorably influence the long-term prognosis of HF. Therapy with digoxin may be initiated at any time to reduce symptoms and enhance exercise tolerance.

**Interventions to be considered for use in selected patients**
Several interventions have been shown in controlled clinical trials to be useful in a limited group of patients with HF. Some of these interventions are being actively investigated in large-scale trials to determine whether it may be appropriate to expand their roles in the management of HF. They include aldosterone antagonists, angiotensin receptor blockers, hydralazine and isosorbide dinitrate, and exercise training.

**Stage D**
**Patients with refractory end-stage HF**
Most patients with HF due to left ventricular systolic dysfunction respond favorably to pharmacological and nonpharmacological treatments and enjoy good quality of life and enhanced survival rates. Some patients, however, do not improve with treatment or have a recurrence of symptoms despite optimal medical therapy. These patients generally have symptoms (including profound fatigue) at rest or with minimal exertion, cannot perform most activities of daily living, frequently have evidence of cardiac cachexia, and typically require repeated or prolonged hospitalizations or intensive management. These individuals represent the most advanced stage of HF and should be considered for specialized treatment strategies such as mechanical circulatory support, continuous intravenous positive inotropic therapy, referral for
cardiac transplantation, or hospice care. Before a patient is considered to have refractory HF, it is critical that physicians confirm the accuracy of the diagnosis; identify and reverse, if possible, any contributing conditions; and ensure that all conventional medical strategies have been optimally employed.

Many patients with advanced HF have symptoms that are related to retention of salt and thus will respond favorably to interventions designed to restore sodium balance. Therefore, a critical step to successful management of end-stage HF is detection and meticulous control of fluid retention.

**Beta-blockers** (see Table 2 at end of guideline)
Recent controlled clinical trials demonstrate that the addition of beta-blockers to recommended therapy for CHF improves the long-term survival of patients. Specifically, clinically stable patients with EF + or - 40% at stages B through D would benefit from the use of beta-blockers. Patients with CHF who do not have a contraindication should have an appropriate trial on beta-blockers. Specific medications used in the larger clinical trials were Metoprolol, bisoprolol (Zebeta), and carvedilol (Coreg). The dose of beta-blockers needs to be titrated over approximately two months to avoid worsening of CHF symptoms. The introduction of beta-blockers may best be co-managed with a cardiologist unless the primary care physician is experienced in the management of CHF with beta-blockers.

**Spiroolactone**
An aldosterone receptor antagonist, spironolactone (Aldactone and others) has been FDA-approved for many years for the treatment of edema, hypertension, and primary hyperaldosteronism. Recently spironolactone was reported to decrease morbidity and mortality in patients with severe heart failure.

The results of a large randomized study indicate that low doses of spironolactone decrease hospitalization and mortality in patients with severe heart failure who are already taking an ACE inhibitor. Based on these results, spironolactone may be considered as part of standard treatment for CHF. The effect of spironolactone on patients with less than severe chronic heart failure remains to be determined.

**Patient management**
Patients diagnosed with heart failure should be counseled on their drug treatment, dietary restrictions, fluid monitoring, and management of their condition. Patient education should be done in conjunction with the initiation of pharmacological therapy and should be reinforced regularly.

Patients should be instructed to keep a daily log of their weight and to notify their physician of any weight gain or loss of more than three pounds. Patients should be instructed to restrict their sodium intake, keeping as close to two grams per day as possible. Alcohol consumption should be discouraged and limited to no more than one drink per day (e.g., one glass of beer or wine, or a cocktail containing no more than one ounce of alcohol). Regular exercise, under physician supervision, should be encouraged.

**Follow-up** (see Table 2 at end of guideline)
If a patient remains symptomatic on ACE inhibitors, diuretics, and digoxin or alternative therapies, the physician may want to consider consultation or co-management with a cardiologist. If a patient is stable on optimal therapies, follow-up by the physician should be done every three months. Due to the risk of hyperkalemia, patients on both ACE inhibitors and spironolactone should periodically have their potassium measured.
### Table 3: Stages in the Evolution of Heart Failure—Recommended Therapy by Stage

<table>
<thead>
<tr>
<th>Stage A</th>
<th>Stage B</th>
<th>Stage C</th>
<th>Stage D</th>
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<tr>
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<td><strong>Stage Criteria</strong></td>
<td><strong>Stage Criteria</strong></td>
<td><strong>Stage Criteria</strong></td>
</tr>
<tr>
<td>At high risk for heart failure but without structural heart disease or symptoms of HF</td>
<td>Structural heart disease but without symptoms of HF</td>
<td>Structural heart disease with prior or current symptoms of HF</td>
<td>Refractory HF requiring specialized interventions</td>
</tr>
<tr>
<td><strong>Example Conditions</strong></td>
<td><strong>Example Conditions</strong></td>
<td><strong>Example Conditions</strong></td>
<td><strong>Example Conditions</strong></td>
</tr>
<tr>
<td>• Hypertension</td>
<td>• Previous MI</td>
<td>• Known structural heart disease</td>
<td>Patients who have marked symptoms at rest despite maximal medical therapy (e.g., those who are recurrently hospitalized or cannot be safely discharged from the hospital without specialized interventions)</td>
</tr>
<tr>
<td>• Coronary artery disease</td>
<td>• LV systolic dysfunction</td>
<td>• Shortness of breath and fatigue, reduced exercise tolerance</td>
<td></td>
</tr>
<tr>
<td>• Diabetes mellitus</td>
<td>• Asymptomatic valvular disease</td>
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</tr>
<tr>
<td><strong>Or</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>• Patients using cardiotoxins</td>
<td></td>
<td></td>
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<tr>
<td>• Patients with FHx CM</td>
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<td></td>
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<td></td>
<td></td>
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<tr>
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<td><strong>Treatment Protocol</strong></td>
<td><strong>Treatment Protocol</strong></td>
<td><strong>Treatment Protocol</strong></td>
</tr>
<tr>
<td>• Treat hypertension</td>
<td>• All measures under Stage A</td>
<td>• All measures under Stage A</td>
<td>• All measures under Stages A, B, and C</td>
</tr>
<tr>
<td>• Encourage smoking cessation</td>
<td>• ACE inhibitors for appropriate patients&lt;sup&gt;2&lt;/sup&gt;</td>
<td>• Drugs for routine use:</td>
<td>• Mechanical assist devices</td>
</tr>
<tr>
<td>• Treat lipid disorders</td>
<td>• Beta-blockers for appropriate patients&lt;sup&gt;3&lt;/sup&gt;</td>
<td>o Diuretics</td>
<td>• Heart transplantation</td>
</tr>
<tr>
<td>• Encourage regular exercise</td>
<td></td>
<td>o ACE inhibitors</td>
<td></td>
</tr>
<tr>
<td>• Discourage alcohol intake, illicit drug use</td>
<td></td>
<td>o Beta-blockers</td>
<td>Continuous (not intermittent) IV inotropic infusions for palliation</td>
</tr>
<tr>
<td>• ACE inhibitors for appropriate patients&lt;sup&gt;1&lt;/sup&gt;</td>
<td></td>
<td>o Digitalis</td>
<td>• Hospice care</td>
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</tbody>
</table>

<sup>1</sup> Patients with Hx of atherosclerotic vascular disease, diabetes mellitus, or hypertension and associated cardiovascular risk factors.

<sup>2</sup> Patients with recent or remote history of MI regardless of EF; with reduced EF whether or not they have experienced MI.

<sup>3</sup> Patients with recent MI regardless of EF; with reduced EF regardless of MI.
Medications in boldface type are preferred agents on the HMSA SELECT formulary and/or the formulary for HMSA QUEST.

**Table 2: Drugs commonly used for heart failure**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Brand</th>
<th>Initial Dose</th>
<th>Maximum Dose</th>
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<td><strong>LOOP Diuretics</strong>¹</td>
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<td></td>
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<tr>
<td>Bumetanide²</td>
<td>generic</td>
<td>0.5 to 2 mg once or twice daily</td>
<td>Titrate to achieve dry weight (up to 10 mg daily)</td>
</tr>
<tr>
<td>Furosemide</td>
<td>generic</td>
<td>20 to 40 mg once or twice daily</td>
<td>Titrate to achieve dry weight (up to 400 mg daily)</td>
</tr>
<tr>
<td>Torsemide²</td>
<td>generic</td>
<td>10 to 20 mg once or twice daily</td>
<td>Titrate to achieve dry weight (up to 200 mg daily)</td>
</tr>
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</tr>
<tr>
<td>Captopril</td>
<td>generic</td>
<td>6.25 mg three times daily</td>
<td>50 mg three times daily</td>
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<tr>
<td>Enalapril²</td>
<td>generic</td>
<td>Enalapril 2.5 mg twice daily</td>
<td>10 to 20 mg twice daily</td>
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<td>Fosinopril</td>
<td>Monopril</td>
<td>5 to 10 mg once daily</td>
<td>40 mg once daily</td>
</tr>
<tr>
<td>Lisinopril</td>
<td>generic</td>
<td>2.5 to 5.0 mg once daily</td>
<td>20 to 40 mg once daily</td>
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<tr>
<td>Quinapril</td>
<td>Accupril</td>
<td>10 mg twice daily</td>
<td>40 mg twice daily</td>
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<tr>
<td>Ramipril</td>
<td>Altace</td>
<td>1.25 to 2.5 mg once daily</td>
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<td>Bisoprolol³</td>
<td>generic</td>
<td>1.25 mg once daily</td>
<td>10 mg once daily</td>
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<tr>
<td>Carvedilol</td>
<td>Coreg</td>
<td>3.125 mg twice daily</td>
<td>25 mg twice daily; 50 mg twice daily for patients greater than 85 kg</td>
</tr>
<tr>
<td>Metoprolol tartrate³</td>
<td>generic</td>
<td>6.25 mg twice daily</td>
<td>75 mg twice daily</td>
</tr>
<tr>
<td>Metoprolol succinate extended release⁴</td>
<td>Toprol XL</td>
<td>12.5 to 25 mg daily</td>
<td>200 mg once daily</td>
</tr>
<tr>
<td><strong>Digitalis Glycosides</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Digoxin</td>
<td>Lanoxin</td>
<td>0.125 to 0.25 mg once daily</td>
<td>0.125 to 0.25 mg once daily</td>
</tr>
</tbody>
</table>
Hypertension

Introduction

Hypertension affects approximately 50 million individuals in the United States and approximately 1 billion worldwide. As the population ages, the prevalence of hypertension will increase even further unless broad and effective preventive measures are implemented. Recent data from the Framingham Heart Study suggest that individuals who are normotensive at age 55 have a 90 percent lifetime risk for developing hypertension.1

The relationship between blood pressure and risk of CVD events is continuous, consistent, and independent of other risk factors. The higher the blood pressure, the greater is the chance of heart attack, heart failure, stroke, and kidney disease. For individuals 40-70 years of age, each increment of 20 mmHg in systolic BP (SBP) or 10 mmHg in diastolic BP (DBP) doubles the risk of CVD across the entire BP range from 115/75 to 185/115 mmHg.2

The new classification “prehypertension,” introduced in these guidelines (see Table 1), recognizes this relationship and signals the need for increased education of health care professionals and the public to reduce BP levels and prevent the development of hypertension in the general population.3 Hypertension prevention strategies are available to achieve this goal (see Table 2).

Goals/Desired Outcomes

In clinical trials, antihypertensive therapy has been associated with reductions in stroke incidence averaging 35-40 percent; myocardial infarction, 20-25 percent; and heart failure, more than 50 percent.4 It is estimated that in patients with stage 1 hypertension (SBP 140-159 mmHg and/or DBP 90-100 mmHg) and additional cardiovascular risk factors, achieving a sustained 12 mmHg reduction in SBP over 10 years will prevent 1 death for every 11 patients treated. In the presence of CVD or target organ damage, only nine patients would require such BP reduction to prevent a death.5

Diagnosis

The auscultatory method of BP measurement with a properly calibrated and validated instrument should be used.6 Persons should be seated quietly for at least five minutes in a chair (rather than on an exam table), with feet on the floor, and arm supported at heart level. Measurement of BP in the standing position is indicated periodically, especially in those at risk for postural hypotension. An appropriately-sized cuff (cuff bladder encircling at least 80 percent of the arm) should be used to ensure accuracy. At least two measurements should be made. SBP is the point at which the first of two or more sounds is heard (phase 1), and DBP is the point before the disappearance of sounds (phase 5). Clinicians should provide to patients, verbally and in writing, their specific BP numbers and BP goals.
Guideline Summary

- In persons older than 50 years, systolic blood pressure greater than 140 mmHg is a much more important cardiovascular disease (CVD) risk factor than diastolic blood pressure.
- The risk of CVD beginning at 115/75 mmHg doubles with each increment of 20/10 mmHg.
- Individuals who are normotensive at age 55 have a 90 percent lifetime risk for developing hypertension.
- Individuals with a systolic blood pressure of 120-130 mmHg or a diastolic blood pressure of 80-89 mmHg should be considered as prehypertensive and require health-promoting lifestyle modifications to prevent CVD.
- Thiazide-type diuretics should be used in drug treatment for most patients with uncomplicated hypertension, either alone or combined with drugs from other classes. Certain high-risk conditions are compelling indications for the initial use of other antihypertensive drug classes (angiotensin converting enzyme inhibitors, angiotensin receptor blockers, beta-blockers, calcium channel blockers).
- Most patients with hypertension will require two or more antihypertensive medications to achieve goal blood pressure (<140/90 mmHg, or <130/80 mmHg for patients with diabetes or chronic kidney disease).
- If blood pressure is > 20/10 mmHg above goal blood pressure, consideration should be given to initiating therapy with two agents, one of which usually should be a thiazide-type diuretic.
- The most effective therapy prescribed by the most careful clinician will control hypertension only if patients are motivated. Motivation improves when patients have positive experiences with, and trust in, the clinician. Empathy builds trust and is a potent motivator.

Table 1: Classification and management of blood pressure in adults

<table>
<thead>
<tr>
<th>BP CLASSIFICATION</th>
<th>SBP MMHG</th>
<th>DBP MMHG</th>
<th>LIFESTYLE MODIFICATION</th>
<th>INITIAL DRUG THERAPY</th>
</tr>
</thead>
<tbody>
<tr>
<td>NORMAL</td>
<td>&lt;120</td>
<td>and &lt;80</td>
<td>Encourage</td>
<td>No antihypertensive drug indicated</td>
</tr>
<tr>
<td>PREHYPERTENSION</td>
<td>120-139</td>
<td>or 80-89</td>
<td>Yes</td>
<td>Drug(s) for compelling indications.</td>
</tr>
<tr>
<td>STAGE 1 HYPERTENSION</td>
<td>140-159</td>
<td>Or 90-99</td>
<td>Yes</td>
<td>Thiazide-type diuretics for most. May consider ACEI, ARB, BB, CCB, or combination.</td>
</tr>
<tr>
<td>STAGE 2 HYPERTENSION</td>
<td>≥160</td>
<td>or ≥100</td>
<td>Yes</td>
<td>Two-drug combination for most (usually thiazide-type diuretic and ACEI or ARB or BB or CCB).</td>
</tr>
</tbody>
</table>

DBP, diastolic blood pressure; SBP, systolic blood pressure.

Drug abbreviations: ACEI, angiotensin converting enzyme inhibitor; ARB, angiotensin receptor blocker; BB, beta-blocker; CCB, calcium channel blocker.

*Treatment determined by highest category.

*Initial combined therapy should be used cautiously in those at risk for orthostatic hypotension.

*Treat patients with chronic kidney disease or diabetes to BP goal of <130/80 mmHg.
Indications for Ambulatory Blood Pressure Monitoring (ABPM) are still unsettled\textsuperscript{18}. ABPM may be helpful for evaluation of “white-coat” hypertension in the absence of target organ injury. It is also helpful to assess patients with apparent drug resistance, hypotensive symptoms with antihypertensive medications, episodic hypertension, and autonomic dysfunction. The ambulatory BP values are usually lower than clinic readings. Awake, individuals with hypertension have an average BP of more than 135/85 mmHg and during sleep, more than 120/75 mmHg. The level of BP measurement by using ABPM correlates better than office measurements with target organ injury.\textsuperscript{8} ABPM also provides a measure of the percentage of BP readings that are elevated, the overall BP load, and the extent of BP reduction during sleep. In most individuals, BP decreases by 10 to 20 percent during the night; those in whom such reductions are not present are at increased risk for cardiovascular events.

BP self-measurements may benefit patients by providing information on response to antihypertensive medication, improving patient adherence with therapy, and in evaluation of white-coat hypertension. Persons with an average BP more than 135/85 mmHg measured at home are generally considered to be hypertensive. Home measurement devices should be checked regularly for accuracy.

Evaluation of patients with documented hypertension has three objectives: (1) to assess lifestyle and identify other cardiovascular risk factors or concomitant disorders that may affect prognosis and guide treatment; (2) to reveal identifiable causes of high BP; and (3) to assess the presence or absence of target organ damage and CVD. The data needed are acquired through medical history, physical examination, routine laboratory tests, and other diagnostic procedures. The physical examination should include an appropriate measurement of BP, with verification in the contralateral arm; examination of the optic fundi; calculation of body mass index (BMI) (measurement of waist circumference may also be useful); auscultation for carotid, abdominal, and femoral bruits; palpation of the thyroid gland; palpation of the lower extremities for edema and pulses; and neurological assessment.

Routine laboratory tests recommended before initiating therapy include an electrocardiogram; urinalysis; blood glucose and hematocrit; serum potassium, creatinine or GFR, and calcium;\textsuperscript{10} and a lipid profile, after a 9- to 12-hour fast that includes high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, and triglycerides.

**Treatment**

A adoption of healthy lifestyles is critical for the prevention of high BP and is an indispensable part of the management of those with hypertension. (See Table 2.)

There are excellent clinical outcome trial data proving that lowering BP with several classes of drugs, including angiotensin converting enzyme inhibitors (ACEIs), angiotensin receptor blockers (ARBs), beta-blockers (BBs), calcium channel blockers (CCBs), and thiazide-type diuretics, will all reduce the complications of hypertension. (See Table 3.)

Resistant hypertension is the failure to reach goal BP in patients who are adhering to full doses of an appropriate three-drug regimen that includes a diuretic. After excluding potential identifiable hypertension, clinicians should carefully explore reasons why the patient is not at goal BP. Particular attention should be paid to diuretic type and dose in relation to renal function. Consultation with a hypertension specialist should be considered if goal BP cannot be achieved. (See Table 1.)
### Table 2: Lifestyle modifications to manage hypertension 1,2

<table>
<thead>
<tr>
<th>MODIFICATION</th>
<th>RECOMMENDATION</th>
<th>APPROXIMATE SBP REDUCTION (RANGE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight reduction</td>
<td>Maintain normal body weight (body mass index 18.5-24.9 kg/m²)</td>
<td>5-20 mmHg/10kg weight loss 23,24</td>
</tr>
<tr>
<td>Adopt DASH eating plan</td>
<td>Consume a diet rich in fruits, vegetables, and lowfat dairy products with a reduced content of saturated and total fat.</td>
<td>8-14 mmHg 25,26</td>
</tr>
<tr>
<td>Dietary sodium reduction</td>
<td>Reduce dietary sodium intake to no more than 100 mmol per day (2.4 sodium or 6 g sodium chloride).</td>
<td>2-8 mmHg 25-27</td>
</tr>
<tr>
<td>Physical activity</td>
<td>Engage in regular aerobic physical activity such as brisk walking (at least 30 min per day, most days of the week).</td>
<td>4-9 mmHg 28,29</td>
</tr>
<tr>
<td>Moderation of alcohol consumption</td>
<td>Limit consumption to no more than 2 drinks (1 oz or 30 mL ethanol; e.g., .24 oz beer, 10 oz wine, or 3 oz 80-proof whiskey) per day in most men and to no more than 1 drink per day in women and lighter weight persons.</td>
<td>2-4 mmHg 30</td>
</tr>
</tbody>
</table>

DASH, Dietary Approaches to Stop Hypertension

1 For overall cardiovascular risk reduction, stop smoking.

2 The effects of implementing these modifications are dose and time dependent, and could be greater for some individuals.

### Table 3: Clinical trial and guideline basis for compelling indications for individual drug classes

<table>
<thead>
<tr>
<th>COMPELLING INDICATION*</th>
<th>RECOMMENDED DRUGS</th>
<th>CLINICAL TRIAL BASIS2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart failure</td>
<td>Diuretic BB ACEI ARB CCB ALDO ANT</td>
<td>ACC/AHA Heart Failure Guideline, MERIT-HF, COPERNICUS, CIBIS, SOLVD, AIRE, TRACE, ValsHeFT, RALES</td>
</tr>
<tr>
<td>Postmyocardial infarction</td>
<td></td>
<td>ACC/AHA Post-MI Guideline, BHAT, SAVE, Capricorn, EPHESUS</td>
</tr>
<tr>
<td>High risk coronary disease</td>
<td></td>
<td>ALLHAT, HOPE, ANBP2, LIFE, CONVINCE</td>
</tr>
<tr>
<td>Diabetes</td>
<td></td>
<td>NKF-ADA Guideline, UKPDS, ALLHAT</td>
</tr>
<tr>
<td>Chronic kidney disease</td>
<td></td>
<td>NKF Guideline, Captopril Trial, RENAAAL, IDNT, REIN, AASK</td>
</tr>
<tr>
<td>Recurrent stroke prevention</td>
<td></td>
<td>PROGRESS</td>
</tr>
</tbody>
</table>

*Compelling indications for antihypertensive drugs are based on benefits from outcome studies or existing clinical guidelines; the compelling indication is managed in parallel with the BP.

1 Drug abbreviations: ACEI, angiotensin converting enzyme inhibitor; ARB, angiotensin receptor blocker; Aldo ANT, aldosterone antagonist; BB beta-blocker; CCB, calcium channel blocker.

2 Conditions for which clinical trials demonstrate benefit of specific classes of antihypertensive drugs.
Hypertension

Treatment Algorithm (JNC VII)

LIFESTYLE MODIFICATIONS

Not at Goal Blood Pressure (<140/90 mmHg) (<130/80 mmHg for patients with diabetes or chronic kidney disease)

INITIAL DRUG CHOICES

Without compelling indications

Stage 1 Hypertension (SBP 140-159 or DBP 90-99 mm Hg)
Thiazide-type diuretics for most. May consider ACEI, ARB, BB, CBB, or combination.

Stage 1 Hypertension (SBP ≥ 160 or DBP ≥ 100 mm Hg)
Two-drug combination for most (usually thiazide-type diuretic and ACEI, or ARB, or BB, or CCB).

With compelling indications

Drug(s) for the compelling indications (See table 3)
Other antihypertensive drugs (diuretics, ACEI, ARB, BB, CCB) as needed.

NOT AT GOAL BLOOD PRESSURE

Optimize dosages or add additional drugs until goal blood pressure is achieved.
Consider consultation with hypertension specialist.


Ischemic Cerebrovascular Disease
Secondary Prevention

Introduction
An ischemic cerebrovascular accident is an acute clinical event that causes impaired blood flow within the brain and the loss of neurological function. Ischemic cerebrovascular accidents (CVAs) are caused by:

- Embolic phenomena
- Extracranial arterial disease
- Intracranial arterial occlusion

Ischemic cerebrovascular disease is divided into two broad categories: thrombotic and embolic. The precise cause of ischemia often cannot be determined.

Diagnosis
Thrombotic strokes occur without warning symptoms in 80 to 90 percent of patients. Between 10 and 20 percent are heralded by one or more transient ischemic attacks. Patients with thrombotic strokes often present with stuttering and fluctuating symptoms that worsen over several minutes or hours.

Patients with embolic strokes usually present with neurological deficit that is maximal at onset. Established risk factors include increased age, smoking, hypertension, previous strokes, diabetes, atrial fibrillation, and transient ischemic attacks. Strokes have catastrophic consequences, often including long-term disabilities. Secondary preventive measures have been shown to impact the recurrence rate of stroke.

Treatment
Post-CVA medical management
The medical management of patients who have survived a CVA is, in part, directed at the underlying causes of the stroke. Appropriate rehabilitation and supportive services are essential to the recovery from a CVA. In cases where the stroke was caused by atrial fibrillation or severe cardiomypathy, patients are very likely to have embolic events. The identification by echocardiogram of a left atrial thrombus increases the certainty of the diagnosis, but lacks sensitivity to be clinically useful. Most patients with atrial fibrillation should be managed with warfarin. Refer to the “Atrial Fibrillation” clinical guidelines in this section.

Note: Post-CVA clinical practice guidelines focus on patients who have had a thrombotic event rather than an embolic event.

REFERENCE


WEBSITE
http://jama.ama-assn.org/issues/v281n12/FFull/jst80021.html
http://www.medicalcrossfire.com/debate_archive/2000/may_00/secondarystroke.htm

GUIDELINE DATE
November 18, 2003

Guideline Summary
- This guideline summary provides recommendations for the secondary prevention of patients with previous ischemic strokes
- Post-CVA medical management is directed at the underlying cause of the stroke
- ASA is the primary form of medical therapy
1. **Indicated medications**
   A cetysalicylic acid (ASA) is the primary form of medical therapy. For patients who have contraindications or are unable to tolerate ASA, antiplatelet agents such as ticlopidine (Ticlid) and clopidogrel (Plavix) are recommended. For patients who have strokes while taking ASA, the general consensus is to use a combination of Aggrenox, Ticlid and ASA, or Plavix and ASA, despite the lack of large randomized controlled trials demonstrating efficacy.

2. **Management of comorbid conditions**
   - The most important aspect of secondary prevention of ischemic CVAs is the appropriate evaluation and treatment for comorbid conditions.
   - **Hypertension.** Long-term management of hypertension is important. Evidence suggests that overly aggressive blood pressure management during and shortly after an acute event may increase morbidity. Although there are no studies that clearly identify a target blood pressure, the Guidelines from the Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC VII) recommend treating patients to a goal of 140/90.
   - **Hyperlipidemia.** See clinical guidelines on “Cholesterol Risk Stratification and Treatment” in this section.
   - **Diabetes.** See clinical guidelines on “Diabetes” in this section.
   - **Atrial fibrillation.** See clinical guidelines on “Atrial Fibrillation” in this section.

3. **Counseling about lifestyle changes**
   - **Cigarette Cessation.** Patients who smoke need to be continually counseled to stop smoking. (See clinical guidelines on “Smoking Cessation” in the Preventive Health section.)
   - **Exercise.** Patients, particularly those who are obese, should initiate and maintain an exercise regimen in accordance with their current health conditions and under their physician's guidance.
   - **Diet.** It is generally prudent to recommend a diet that is low in salt and with less than 30 percent of calories from fat.

4. **Surgery**
   - Carotid endarterectomy has been found beneficial for patients who had a stroke or experienced warning signs of stroke and had a severe stenosis of greater than 70%.
Ischemic Cerebrovascular Disease

History and Physical
Assess total cardiovascular risk. Identify source of CVA if not established, embolic, associated atrial fibrillation or cardiac arrhythmia, severe cardiomyopathy, carotid or vertebral artery stenosis, peripheral vascular disease.

Diagnostic evaluation
Based on the H&P, patients should have additional evaluation that may include: Lipid panel, blood glucose, electrolytes, BUN, Creatinine, cardiac evaluation, EKG, echo cardiogram, duplex carotid angiogram, cerebral imaging study.

Management of comorbidities
- Cholesterol: Target LDL <100mg (see Cholesterol guidelines)
- Diabetes: Target Hb A1c ≤ 7.0
- See Hawaii State Recommendations for Diabetes Care
- Hypertension: goal <140/90 BP (see Hypertension guidelines)

Lifestyle changes
- Stop smoking
- Cardiac rehabilitation/exercise
- Weight management for obese patients
- Dietary counseling

History of ASA use prior to CVA

ASA therapy
ASA 81-325 mg daily
Recommended for all patients. Alternative platelet inhibitors are recommended for patients unable to take ASA.

Patient with previous ischemic cerebrovascular accident (CVA)

YES

Warfarin anticoagulation: see Atrial Fibrillation guidelines

NO

Diagnostic evaluation: see Atrial Fibrillation guidelines

YES

Continue medication therapy indefinitely provided the patient can tolerate the medications.

NO

Patients with embolic strokes, atrial fibrillation or severe cardiomyopathy

YES

Management of comorbidities

History and Physical

Diagnostic evaluation

Lifestyle changes

History of ASA use prior to CVA

ASA therapy

Aggrenox, Ticlid and ASA or Plavix and ASA combination therapy
Introduction

Acute myocardial infarction (AMI) is one of the most common diagnoses of hospitalized patients in industrialized countries. In the United States, approximately 1.5 million myocardial infarctions occur each year. The mortality rate of AMI is approximately 30 percent, with more than half of these deaths occurring before the stricken individual reaches the hospital. In recent decades in-hospital mortality has decreased. Approximately one in 25 patients who survives the initial hospitalization dies in the first year after myocardial infarction. Survival is markedly decreased in elderly patients over age 65 whose mortality rate is 20 percent at one month and 35 percent at one year. Secondary prevention measures have been shown to impact the mortality rate in patients who have experienced a myocardial infarction.

Goals/Desired Outcomes

Increase the timely initiation of treatment to reduce post-infarction mortality in patients with AMI. Possible measurable results:

- Percentage of patients with AMI receiving beta-blockers initiated prior to discharge, for whom this treatment is appropriate.
- Percentage of patients with AMI placed on prophylactic aspirin initiated prior to discharge, for whom this treatment is appropriate.
- Percentage of patients with AMI receiving ACE inhibitors initiated prior to discharge, for whom this treatment is appropriate.
- Percentage of patients with AMI receiving statin agent initiated prior to discharge, for whom this treatment is appropriate.

Treatment

The approach to secondary prevention for patients with a previous AMI but without a history of percutaneous transluminal coronary angioplasty (PTCA) or coronary artery bypass graft (CABG) includes attention to indicated medications, management of comorbid conditions and counseling about lifestyle changes. The following is a list of recommended therapies for patients who have had a previous AMI.

Guideline Summary

- This guideline focuses on secondary prevention of acute myocardial infarction.
- Recommended medical therapy for patients with previous AMI:
  - ASA
  - Beta-blockers
  - ACE inhibitors
  - Statin therapy for LDL ≤ 100 mg/dL

REFERENCES


WEBSITE

http://www.icsi.org/guide/AMI.pdf
http://www.acponline.org/journal/annals/01apr97/coroncar.htm
http://www.acc.org/clinical/guidelines/nov96/1999/index.htm

GUIDELINE DATE
November 18, 2003
1. **Indicated medications**
   - **Beta-blockers.** Beta-blockers reduce future events in post-AMI patients and in patients with diabetes or reactive airways. The benefit of beta-blockers occurs in patients with comorbid conditions (diabetes or chronic obstructive pulmonary disease) should be tried on beta-blockers, with the medication discontinued only if there are clinical side effects of the therapy. Propranolol, timolol and metoprolol have been used in the largest randomized controlled trials, but there is no evidence that the benefits are not a class effect.
   - **Acetylsalicylic acid.** As treatment, acetylsalicylic acid (ASA) has been shown to reduce events in the primary prevention of heart attacks. Six randomized studies have established an approximate 13 percent relative risk reduction in post-infarct patients with long-term use. The secondary prevention dosage range was 300 to 1500 mg/day. A more recent study shows a 34 percent improvement in nonfatal AMIs and death using a dose of 75 mg/day. The lower dose is as effective with fewer side effects and is generally the recommended dose. Studies have not shown that other antiplatelet agents have advantages over aspirin.
   - **ACE inhibitors.** The long-term use of an angiotensin converting enzyme (ACE) inhibitor reduces mortality in post-AMI patients. There appears to be a beneficial physiologic effect of the post-MI cardiac remodeling. Current literature supports the use of ACE inhibitors in all patients with MIs or decreased left ventricular ejection fraction. Maximum risk reduction is in patients with congestive heart failure.
   - **Statin therapy.** The large majority of patients who have an acute MI have high serum lipid levels. Lipid treatment, including administration of statins, should be addressed as soon as possible. A patient’s lipid status should be determined within the first 24 hours. If the LDL level is \( \geq 100 \text{ mg/dL} \), the patient should be started on a statin.
2. Management of comorbid conditions
   • **Hypertension—evaluation and treatment.** The goal for post-AMI patients should be blood pressure \(<130/85\), or \(<130/80\) in diabetic patients. (See clinical guidelines on “Hypertension” in this section).
   • **Hyperlipidemia—evaluation and treatment.** The goal for post-AMI patients should be LDL below 100 mg/dL. (See clinical guidelines on “Cholesterol Risk Stratification and Treatment” in this section).
   • **Diabetes—evaluation and treatment.** The goal for post-AMI patients should be HbA1c below 7.0 percent. (See clinical guidelines on “Diabetes, Hawaii State Practice Recommendations” in section 10.)
   • **Obesity.** Patients should be counseled to reduce weight to a BMI of 18.5 - 24.9 kg/m².
   • **Hormonal Replacement Therapy (HRT) after AMI.** Postmenopausal women who are already taking HRT with estrogen plus progestin should stop HRT after acute events.

3. Counseling about lifestyle changes
   • **Cigarette cessation.** Patients who smoke need to be continually counseled to stop smoking. (See clinical guidelines on “Smoking Cessation” in the Preventive Health section.)
   • **Exercise.** Patients, particularly those who are obese, should initiate and maintain an exercise regimen in accordance with their current health conditions and under their physician's guidance.
   • **Diet.** It is generally prudent to recommend a diet low in salt and with less than 30 percent of calories from fat.
Introduction

Diabetes mellitus (DM) is a group of disorders that lead to hyperglycemia due to impairment in the body's secretion (Type 1) or utilization (Type 2 and gestational) of insulin. Type 2 Diabetes may be considered more insidious because it is often asymptomatic early on and may lay undiagnosed for many years. Comprehensive diabetes management substantially reduces the short and long term complications of DM. According to the CDC, diabetes had affected approximately 17 million Americans by 2000. Because of the high Asian Pacific Islander populations, Hawaii has one of the highest rates of DM in the United States. The likelihood of a patient with diabetes, discovered or not, showing up in a typical medical practice, is great.

Note: Any reference to the Hemoglobin A1c test (HbA1c) will be made as A1c in this document.

Diagnosis

Generally two clinical tests serve as reliable indicators of DM: fasting plasma glucose (FPG) and the oral glucose tolerance test (OGTT). The diagnostic parameters of these tests are summarized in the table below (source: Diabetes Care, Vol 24, Supplement 1, January 2001, S21-S24).

### Diagnostic Indicators of DM

<table>
<thead>
<tr>
<th>DIAGNOSIS</th>
<th>FASTING</th>
<th>ORAL GLUCOSE TOLERANCE TEST (2-HOUR POST LOAD OGTT)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal glucose</td>
<td>&lt;100</td>
<td>&lt;140 mg/dL</td>
</tr>
<tr>
<td>Either: Impaired Glucose Tolerance (IGT) or Impaired Fasting Glucose (IFG)</td>
<td>110-125</td>
<td>140-199 mg/dL</td>
</tr>
<tr>
<td>Diabetes</td>
<td>≥ 126</td>
<td>≥ 200 mg/dL</td>
</tr>
</tbody>
</table>

**Additional diagnostic criteria from the American Diabetes Association**
- Fasting blood glucose (FBG) ≥ 126 mg/dL is an indication for retesting, which should be repeated on a different day to confirm diagnosis.
- Symptoms of diabetes and a casual plasma glucose level of 200 mg/dL also establishes the diagnosis of diabetes.
- A 2-hour post load value in the OGTT of 200 mg/dL should be confirmed on an alternate day.
- OGTT is appropriate in a patient where the diagnosis is in question.

**REFERENCE**


**WEBSITE**
http://www.diabetes.org
http://www.state.hi.us/doh/resource

**GUIDELINE DATE**
November 18, 2003
Principle 1: Screening high-risk patients and diagnosing diabetes

One-third of people with diabetes remain undiagnosed. Finding and treating diabetes early can improve health outcomes. Therefore, routine screening and correct diagnosis are essential.

**Screening recommendations**

<table>
<thead>
<tr>
<th>POPULATIONS (ADA RECOMMENDATIONS)</th>
<th>FREQUENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td>People 45 years or older with no risk factors</td>
<td>Every 3 years FBS preferred test</td>
</tr>
<tr>
<td>People with risk factors</td>
<td>Screen more frequently and at younger age group based on risk factors</td>
</tr>
</tbody>
</table>

Principle 2: On-Going Care

People with diabetes should receive high-quality care on an ongoing basis to ensure that they are managing their diabetes, and to make changes to their treatment plan when needed to achieve control of the disease.

**Physical (primary provider) follow-up for patients with diabetes**

<table>
<thead>
<tr>
<th>POPULATION</th>
<th>FREQUENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients under good metabolic control (Blood Sugar, Blood Pressure, Cholesterol)</td>
<td>Minimal visits 2 per year</td>
</tr>
<tr>
<td>Patients not reaching goals in one or more areas or patients with co-morbid conditions</td>
<td>Visits as required to obtain metabolic control and good diabetes management: &gt; 2 visits per year</td>
</tr>
</tbody>
</table>

Principle 3: Diabetes education

People with diabetes and their family members have the right to accurate information and education needed for diabetes self-care.

- Requires a team approach
- Includes elements of self care
- Instruction on the prescribed medical regimen
- Addresses needs of the individual and his or her family
- Establishes self-management goals through a collaborative effort with the patient

Health care providers should be responsible for diabetes education that addresses the medical and emotional needs of the individual patient. Diabetes education is a continuous process. It should begin with the essential elements of self-care and include instruction on the prescribed medical regimen. Over time, the instruction should become a dialogue that defines and addresses the needs of the individual and his or her family.
People with diabetes should have the opportunity to acquire the knowledge and skills necessary to provide self-care for their disease. It is also important to enlist the patient, family members, and others who support the patient in the health care team so as to achieve a greater measure of self-care and quality of life for people with diabetes.

**Principle 4: Treating hyperglycemia**

Blood glucose levels should be kept as near to normal levels as is safely possible. The target range should be based on an overall assessment of the patient’s health.

**Blood glucose level indicators**

<table>
<thead>
<tr>
<th>VALUES</th>
<th>NORMAL</th>
<th>GOAL</th>
<th>ADDITIONAL ACTION SUGGESTED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole Blood Values</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average Preprandial Glucose (mg/dL)</td>
<td>&lt;100</td>
<td>80-120</td>
<td>&lt;80 or &gt;140</td>
</tr>
<tr>
<td>Average bedtime glucose (mg/dL)</td>
<td>&lt;110</td>
<td>100-140</td>
<td>&lt;100 or &gt;160</td>
</tr>
<tr>
<td>Serum Blood Values</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average Preprandial Glucose (mg/dL)</td>
<td>&lt;110</td>
<td>90-130</td>
<td>&lt;90 or &gt;150</td>
</tr>
<tr>
<td>Average bedtime glucose (mg/dL)</td>
<td>&lt;120</td>
<td>110-150</td>
<td>&lt;110 or &gt;180</td>
</tr>
<tr>
<td>A1c (%)</td>
<td>&lt; 6</td>
<td>&lt; 7</td>
<td>&gt; 8</td>
</tr>
</tbody>
</table>

**Principle 5: Self-monitoring of blood glucose control and A1c**

Blood glucose levels and A1c values should be measured on a routine basis using current, reliable methods.

**Routine self-monitoring of blood glucose** is the most successful approach in self-management of diabetes because it provides a picture of the immediate blood glucose level. Individual circumstances will define how often self-monitoring is used, the specific approach, and the methods of recording or reporting results.

**A1c—Goals < 7.0 percent**

<table>
<thead>
<tr>
<th>POPULATION</th>
<th>FREQUENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 2 patients with good blood glucose control</td>
<td>Minimal two times a year</td>
</tr>
<tr>
<td>Type 1 patients and patients not in good control</td>
<td>More than two times a year, up to 4-5 times per year.</td>
</tr>
</tbody>
</table>
Principle 6: Preventing and diagnosing long-term diabetes problems
Sound diabetes care can greatly lower the chances of developing long-term problems.

The control of blood glucose is one important way to prevent complications. Other important risk factors include smoking, high blood pressure and levels of blood fats above normal (especially high total cholesterol and LDL-cholesterol, or low HDL-cholesterol levels). Routine measurement and management of these risk factors are part of good diabetes care.

Another important way to prevent long-term complications of diabetes is to practice healthy self-care behaviors. A healthy diet and regular use of prescribed medications are basic behaviors needed for diabetes self-care. Regular exercise, foot care, and routine visits to health care providers are examples of other needed behaviors.

Principle 7: Screening for and treating long-term diabetes problems
People with diabetes should have regular exams to help find and treat long-term diabetes problems. All long-term diabetes problems have effective treatments. (See next page for screening recommendations).
Screening and treatment for long-term diabetes. Based on ADA and NCEP recommendations.

<table>
<thead>
<tr>
<th>PROCEDURE / EXAM</th>
<th>FREQUENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dilated Eye Exam:</strong></td>
<td>Annual for patients with Type 2 diabetes</td>
</tr>
<tr>
<td></td>
<td>Annually for patients with Type 1 diabetes after 5 years from onset.</td>
</tr>
<tr>
<td></td>
<td>By an ophthalmologist or optometrist knowledgeable and experienced in diagnosing diabetic retinopathy. If diabetic retinopathy is detected, follow-up referral to an ophthalmologist who is knowledgeable and experienced in treating diabetic retinopathy.</td>
</tr>
<tr>
<td>Complete foot examination including monofilament testing</td>
<td>Annually complete for all patients and foot inspection on every visit for patients with increased risk of foot problems</td>
</tr>
<tr>
<td>Assessment for renal disease</td>
<td>Patients with renal insufficiency (creatinine ≥ 1.5): annual creatinine</td>
</tr>
<tr>
<td></td>
<td>Patients with normal renal function (creatinine &lt; 1.5): annual UA with a reflex microalbuminuria for patients without gross proteinuria</td>
</tr>
<tr>
<td>Blood pressure monitoring and treatment</td>
<td>Blood pressure check at each physician office visit: Treatment goal: &lt;130/80 mmHg</td>
</tr>
<tr>
<td>Lipid monitoring and treatment</td>
<td>Annual lipid profile (May be done every 2 years with previous normal levels)</td>
</tr>
<tr>
<td></td>
<td>• CHD goal LDL &lt;100 mg/dL</td>
</tr>
<tr>
<td></td>
<td>• 30 y and &lt; 65 y with no CVD. Goal for LDL &lt;100 mg/dL</td>
</tr>
<tr>
<td></td>
<td>Medication with therapeutic lifestyle changes (TLC) if LDL &gt;130 mg/dL</td>
</tr>
<tr>
<td></td>
<td>• 65 y with no CHD individualized therapy</td>
</tr>
<tr>
<td></td>
<td>• Under 30 y (No CHD) individualized therapy</td>
</tr>
<tr>
<td></td>
<td>• Use of medication in women with child bearing potential should be initiated only when the woman is fully informed of the risk</td>
</tr>
<tr>
<td>Immunizations</td>
<td>Influenza – annual</td>
</tr>
<tr>
<td></td>
<td>Pneumococcal vaccine – one per lifetime. Repeat vaccine recommended at age 65 for individuals vaccinated 5 years or more prior to age 65.</td>
</tr>
<tr>
<td></td>
<td>Tetanus Diphtheria – every 10 years</td>
</tr>
<tr>
<td>ASA prophylaxis</td>
<td>ASA (Enteric Coated) 81-325 mg/day.</td>
</tr>
<tr>
<td></td>
<td>• Documented CVD</td>
</tr>
<tr>
<td></td>
<td>• High risk for CVD</td>
</tr>
<tr>
<td></td>
<td>• Suggested for patients &gt; 30 y without risk factors.</td>
</tr>
<tr>
<td>ASA prophylaxis</td>
<td>Annual exam</td>
</tr>
</tbody>
</table>
Introduction

Osteoporosis is a condition characterized by thinning and weakening of the bones, leaving them susceptible to fracture. Fractures related to osteoporosis may lead to diminished quality of life, disability, and even death.

Women are at greater risk for osteoporosis and fracture. In postmenopausal women, one half will develop an osteoporosis-related fracture; 25 percent will have a vertebral deformity, and 15 percent will suffer a hip fracture.1 As bone density declines, the risk of fracture increases.

Goal of Treatment

The goal of this guideline is to decrease the incidence of osteoporosis-related fractures to achieve the highest quality of life for individual patients.

Diagnosis

Screening for postmenopausal women

The U.S. Preventive Services Task Force (USPSTF) recommends that routine screening begin at age 60 for women with increased risk of osteoporotic fractures, and that all women aged 65 and older be screened routinely for osteoporosis (USPSTF B recommendation. See Appendix A).

No current use of estrogen and age are incorporated along with low body weight into the three-item Osteoporosis Risk Assessment Instrument (ORAI), which helps clinicians identify women younger than 65 who should be screened2,3 (see http://www.osteoed.org/faq/screening/orai.shtml).

The USPSTF makes no recommendation for or against routine osteoporosis screening in postmenopausal women who are younger than 60, or in women aged 60 to 64 who are not at an increased risk for osteoporotic fractures (USPSTF C recommendation. See Appendix A).

The World Health Organization (WHO) has defined osteoporosis based on bone mineral density (BMD), commonly expressed as a T-score. The T-score represents a patient’s bone density as the number of standard deviations (SD) above or below the mean BMD value for a normal young adult. Osteoporosis is defined by a BMD more than 2.5 SD below the mean for a young, healthy, adult woman. A BMD between 1 and 2.5 SD below the mean is defined as osteopenia.

Risk factors for osteoporotic fractures

- Lower body weight (weight < 70 kg) is the single best predictor of low bone mineral density.2,3
Osteoporosis
Postmenopausal Women

**Osteoporosis—Postmenopausal women**

- Osteoporosis is defined by a BMD > 2.5 SD below a normal young adult woman.
- USPSTF recommends osteoporosis screening in postmenopausal women age 65 and older.
- Risk factors for osteoporotic fractures:
  - Women
  - Weight < 70 kg
  - Increasing age
  - Prior low-trauma fracture
  - Potential for falling increases fracture risk
  - Long-term steroid use
  - Smoking
  - Weight loss
  - Family history - those whose parents have a history of spine or hip fractures.
  - Anorexia, weight loss.
  - Excessive use of alcohol.
  - An inactive lifestyle or extended bed rest.
  - Cigarette smoking.
  - A lifetime diet low in calcium and vitamin D.

**BMD Measurement**
Among different bone measurement tests performed at various anatomical sites, bone mineral density (BMD) measured at the femoral neck by dual-energy x-ray absorptiometry (DXA) is the best predictor of hip fracture and is comparable to forearm measurements for predicting fractures at other sites. DXA of the lumbar spine and proximal femur provides reproducible values. These central sites of osteoporosis-associated fracture are more likely than peripheral sites to demonstrate a response to treatment and are preferred for baseline and serial measurements.

Further research is required to determine the accuracy of peripheral BMD testing in comparison with DXA.

**Laboratory Tests**
The American Association of Clinical Endocrinologists has recommended the following laboratory tests to establish baseline conditions or to definitively exclude secondary causes of osteoporosis, even in the absence of other clinical indications:

- Complete blood cell count
- Serum chemistry (especially calcium, phosphorus, total protein, albumin, liver enzymes, alkaline phosphatase, creatinine, and electrolytes)
- Urinary calcium excretion
- Thyroid function test

Other laboratory tests may be performed to rule out suspected secondary causes of bone loss, and may be found in the American Association of Clinical Endocrinology Postmenopausal Osteoporosis Guidelines (see reference in sidebar).
Prevention

- Ensure an adequate intake of calcium. The National Osteoporosis Foundation recommends 1200mg per day as the recommended daily intake of calcium for postmenopausal women. Good sources of dietary calcium include low-fat dairy products, such as milk, yogurt, ice cream, and cheese; dark green leafy vegetables, such as, broccoli, bok choy, collard greens, and spinach; tofu; almonds; sardines and salmon with bones; and foods fortified with calcium, such as, orange juice, cereals and breads. Calcium supplementation may be required depending the amount of calcium absorbed from foods.

- Vitamin D is important for bone health and calcium absorption. Vitamin D is synthesized from the skin's exposure to sunlight. To ensure the recommended vitamin D levels of 400 to 800 IU, supplements may be required. Excessive vitamin D intake is not recommended.

- Exercise helps prevent osteoporosis by protecting bones. Bone is a living tissue that, like muscles, responds to exercise by becoming stronger. Recommended weight-bearing exercises include: walking, jogging, hiking, tennis, climbing stairs, weight lifting, and dancing.

- Smoking should be discontinued. Women who smoke have lower levels of estrogens and frequently go through menopause earlier than non-smoking women. Smoking may also decrease the absorption of calcium.

- Regular alcohol consumption of two to three ounces a day may be damaging to bone health. Heavy drinkers are more prone to fractures and bone loss because of poor nutrition and increased risk of falling.

- Avoid medications that cause bone loss. Medications including glucocorticoids (long-term use), certain anti-seizure medications such as phenytoin, and barbiturates can cause bone loss. Gonadotropin-releasing hormones analogs used to treat endometriosis, excessive use of aluminum-containing antacids, certain chemotherapies, and excessive thyroid hormone can also contribute to bone loss.

- Prevention medications. See “Therapeutic Medications.”

Treatment

The Fracture Intervention Trial (FIT) results suggest that treatment will produce larger benefits in women with more risk factors for fracture, such as those who are older, have very low bone density, or have pre-existing vertebral fractures. The USPSTF found little evidence regarding which patients are likely to benefit from screening and treatment. It is not known whether women who have a similar overall risk for fracture, but different bone densities, will benefit similarly from treatment. This uncertainty is clinically important because the lack of accepted criteria for initiating treatment remains a problem.
Osteoporosis

Postmenopausal Women

**Exclude Secondary Causes**
Before treatment it is important to exclude secondary causes of osteoporosis by:
- Confirming the diagnosis with DXA if appropriate
- Identifying secondary causes of osteoporosis, e.g., alcohol abuse, hyperparathyroidism or hyperthyroid disease
- Excluding other diseases which may mimic osteoporosis, i.e., osteomalacia or malignancy

The American Association of Clinical Endocrinologists osteoporosis guidelines lists the secondary causes of osteoporosis and suggested tests to rule out suspected secondary causes of osteoporosis.

**Nutritional Considerations**
Calcium and vitamin D are addressed in the “Prevention of Osteoporosis” section.

**Exercise**
Regular weight-bearing exercise increases bone strength, and improves muscle strength, coordination, and balance. See exercise recommendations under the “Prevention of Osteoporosis” section.

**Therapeutic Medications**
Currently, the bisphosphonates (alendronate, risedronate) and raloxifene are approved by the U.S. Food and Drug Administration (FDA) for the prevention and treatment of osteoporosis. The FDA has approved teriparatide for the treatment of osteoporosis in men and women who have a high risk of fracture. While estrogen therapy is approved for prevention, calcitonin is approved for treatment of osteoporosis. Both alendronate and risedronate have FDA indications for use by men and women with glucocorticoid-induced osteoporosis. Alendronate is approved for osteoporosis in men.

**Bisphosphonates**
- Alendronate (brand name Fosamax) reduces bone loss, increases bone density in both the spine and hip, and reduces the risk of spine and hip fractures in postmenopausal women. Uncommon side effects of alendronate may include abdominal or musculoskeletal pain, nausea, heartburn, or irritation of the esophagus. The medication should be taken first thing in the morning with a full glass of water on an empty stomach. It is important to remain upright and avoid food or beverages for at least 30 minutes, or preferably one hour, after taking alendronate.
- Risedronate (brand name Actonel) has been shown to slow or stop bone loss, increase bone mineral density and reduce the risk of spinal and other fractures.
Minimal to moderate side effects reported were similar to the placebo group. Risedronate should be taken in the morning with a large glass of water 30 minutes before eating. It is important to remain upright for 30 minutes after taking risedronate.

**Raloxifene (brand name Evista)**

Raloxifene is from the Selective Estrogen Receptor Modulators (SERMs) drug class. Raloxifene appears to prevent bone loss at the spine, and hip, as well as throughout the body. It has been shown to have beneficial effects on bone mass and bone turnover and can reduce the incidence of vertebral fractures. Reported side effects include hot flashes and deep vein thrombosis. The latter is also associated with estrogen therapy.

**Calcitonin**

Calcitonin is a naturally occurring hormone that helps regulate calcium metabolism and bone metabolism. Calcitonin slows bone loss, increases spinal bone density, and may relieve the pain associated with vertebral fractures. Calcitonin is available as either an injectable or a nasal spray preparation. The injectable calcitonin may cause an allergic reaction, flushing of the face and hands, urinary frequency, nausea, and skin rash. The side effect for nasal spray calcitonin may be runny nose.

**Teriparatide (brand name Forteo)**

Teriparatide is an injectable form of human parathyroid hormone that stimulates new bone formation in the spine and hip. It also reduces the risk of vertebral and non-vertebral fractures in postmenopausal women. Side effects include nausea, dizziness and leg cramps. Teriparatide is approved for up to 24 months of use.

**Estrogen/ hormone therapy**

In postmenopausal women, estrogen/hormone therapy (ET/HT) has been shown to reduce bone loss, increase bone density in both the spine and hip, and reduce the risk of spine and hip fractures. The recent Women’s Health Initiative (WHI) study demonstrated that HT (Prempro) is associated with a modest increase in the risk of breast cancer, stroke and heart attack. The estrogen study is ongoing. The National Cancer Institute (NCI) has recently indicated that long-term ET may be associated with an increase in the risk of ovarian cancer. Any estrogen therapy should be prescribed for the shortest period of time possible.

**Fall prevention**

Falls can increase the probability of fracturing a bone in the hip, wrist, spine or other part of the body, especially in men and women with osteoporosis. Falls may be caused by impaired vision and/or balance, chronic diseases that impair mental or physical functioning, and certain medications such as sedatives and antidepressants. It is important that the physician ask about any physical changes that may affect balance or gait.

- **Outdoors** - use a cane or walker for added stability; wear rubber-soled shoes for traction; walk on grass when sidewalks are slippery.
- **Indoors** - keep rooms free of clutter, especially on floors; keep floor surfaces smooth but not slippery; wear low-heeled shoes; avoid walking in socks, stockings, or house slippers; be sure carpets and area rugs have skid-proof backing or are tacked to the floor; be sure stairwells are well lit and that stairs have handrails.

**BMD to monitor treatment**

Patients treated with bisphosphonates may demonstrate changes in BMD improvement at the spine within a year, and at the hip after two or more years. Although improvement in BMD in the range of 3 to 5% is clinically significant, no change or slight reduction of BMD is not evidence of treatment failure and does not warrant alteration of therapy. To promote consistency, follow-up BMD should be performed every 2 years, at the same anatomical site, and using the same technique whenever possible.
Osteoporosis Screening

USPSTF Osteoporosis Screening in Postmenopausal Women.
> 60 years with increased risk of osteoporotic fractures
≥ 65 years

DXA Scan
(hip desired)

Osteopenia
BMD between 1 and 2.5 SD below the mean

Osteoporosis
BMD more than 2.5 SD below the mean

Normal
BMD greater than/equal to 1 SD below the mean

Osteoporosis Treatment

National Osteoporosis Foundation Recommendation of Treatment Initiation
1. BMD < -2 SD with no risk factors.
2. BMD < -1.5 SD with multiple risk factors.

Secondary Cause of Osteoporosis
Yes → Treat Underlying Disease
No

Treatment
1. Nutrition.
   - Adequate calcium. 1200 mg/D
   - Adequate vitamin D. 400-800 IU/D
2. Regular weight-bearing exercise
3. Avoidance of tobacco use/alcohol abuse
4. Medications* - Bisphosphonates
   - Raloxifene
   - Calcitonin
5. Fall assessment
6. Follow-up DXA every 2 years

*Forteo - for the treatment failure or intolerance to medications
Osteoporosis
Postmenopausal Women

References


Appendix A. USPSTF Recommendations and Ratings

The USPSTF grades its recommendations according to one of five classifications (A, B, C, D, or I), reflecting the strength of evidence and magnitude of net benefit (benefits minus harms):

A. The USPSTF strongly recommends that clinicians routinely provide [the service] to eligible patients. The USPSTF found good evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms.

B. The USPSTF recommends that clinicians routinely provide [the service] to eligible patients. The USPSTF found at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms.

C. The USPSTF makes no recommendation for or against routine provision of [the service]. The USPSTF found at least fair evidence that [the service] can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation.

D. The USPSTF recommends against routinely providing [the service] to asymptomatic patients. The USPSTF found at least fair evidence that [the service] is ineffective or that harms outweigh benefits.

I. The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing [the service]. Evidence that [the service] is effective is lacking, of poor quality, or conflicting and the balance of benefits and harms cannot be determined.
**Introduction**

Acute bronchitis consistently ranks among the 10 conditions that account for most ambulatory office visits. In the U.S., approximately 5 percent of adults self-report an episode of acute bronchitis annually, and up to 90 percent of these patients seek medical care. Most uncomplicated cases occur in otherwise healthy adults.

**Goals/Desired Outcomes**

- Focus on ruling out serious illness, particularly pneumonia, when evaluating adults with an acute cough illness or a presumptive diagnosis of uncomplicated acute bronchitis.
- Avoid prescribing antibiotics for uncomplicated acute bronchitis, regardless of duration of cough. If Bordetella pertussis infection is suspected (an unusual circumstance), a diagnostic test should be performed and antimicrobial therapy initiated. This recommendation applies to immunocompetent adults without complicating comorbid conditions, such as chronic lung or heart disease.
- Remember that effective communication between the physician and the patient contributes more to patient satisfaction than antibiotic treatment.

**Diagnosis**

Diagnosis of acute bronchitis is usually appropriate when the patient presents with an acute respiratory tract infection in which cough, with or without phlegm, is a predominant feature. Using cough, sore throat, rhinorrhea, and other symptoms suggestive of acute upper respiratory tract infection may result in inconsistent diagnoses.

- In the absence of severe airflow obstruction, limit evaluation for possible chronic asthma or cough-variant asthma to patients with cough illness lasting longer than three weeks. The diagnosis of cough-variant asthma is generally reserved for patients with persistent cough (> 2-3 weeks’ duration) that worsens at night or after exposure to cold; lack of wheezing; and in most cases, normal results in pulmonary function.
- An review of evidence-based studies concluded that absence of abnormalities in vital signs (heart rate ≥ 100 beats/ min, respiratory rate ≥ 24 breaths/ min, or oral temperature ≥ 38°C) and chest auscultatory examination (e.g., rales, egophony or fremitus) sufficiently reduces likelihood of pneumonia, making further diagnostic testing unnecessary. Purulent sputum occurs when inflammatory cells or sloughed mucosal epithelial cells are present and can result from either viral or bacterial infection.
High index of suspicion for pneumonia remains warranted in the elderly and patients with chronic lung disease.

Treatment

- Antibiotic treatment of uncomplicated acute bronchitis is not recommended, regardless of duration of cough. Randomized placebo-controlled trials have failed to support a role for antibiotic treatment of uncomplicated acute bronchitis. No consistent impact has been shown on duration or severity of illness, or on potential complications such as the development of pneumonia. Three meta-analyses reported no impact on illness duration, limits of activity or loss of work. All concluded that routine antibiotic treatment of acute bronchitis in adults is not justified.

- Studies to date have been unable to distinguish bacterial bronchitis from viral bronchitis on clinical grounds, except on suspicion of pertussis. However, clinicians should limit suspicion and treatment of adult pertussis to adults with a high probability of exposure to pertussis (e.g., during documented outbreaks). Antimicrobial therapy for suspected pertussis in adults is recommended primarily to decrease shedding of the pathogen and spread of the disease. Public health implications for pertussis include diagnostic testing at local or state health departments.

- Influenza is the most common pathogen isolated in patients with uncomplicated acute bronchitis. Inhaled (zanamivir) and oral (oseltamivir) formulations of neuraminidase inhibitors have demonstrated some efficacy in reducing illness duration in adults with naturally acquired influenza A and B, if treatment begins within 48 hours (preferably < 30 hours) of symptom onset. The result is about one day less of illness, and about a half-day sooner return to normal activity. Accurate clinical diagnoses of influenza outside the annual outbreak period is difficult, and as a result, diagnostic testing for influenza during this period may be considered for epidemiological purposes.

- Symptomatic treatment and reassurance are the preferred initial management strategy for patients with uncomplicated acute bronchitis, beginning with identification of symptoms most bothersome to the patient. If cough is the major symptom, the efficacy of bronchodilators for bronchial hyperresponsiveness has been demonstrated. Efficacy of antitussive treatment will depend on the cause of the cough illness. Acute or early cough due to colds or other viral
upper respiratory tract infections does not appear to be alleviated by dextromethorphan or codeine. However, these drugs may be efficacious in treating chronic cough (duration > three weeks), cough associated with underlying lung disease, or experimentally induced cough. For uncomplicated acute bronchitis with an average duration of cough of two to three weeks, the two agents will have a modest effect on severity and duration. Other low-cost and low-risk actions, such as using a vaporizer and eliminating environmental triggers, are reasonable options.

Patient Satisfaction and Education

Patient satisfaction regarding care for acute bronchitis depends more on communication between the physician and patient than whether an antibiotic is prescribed. Discuss the lack of efficacy of antibiotics with the patient and stop prescribing antibiotics for this condition as a standard practice. The patient’s expectation of receiving antibiotics may derive from previous experiences; however, mounting evidence indicates that patient satisfaction is less dependent on the receipt of antibiotics and more dependent on the quality of the encounter.

Following are recommended educational strategies:

• Provide realistic expectations for the duration of the patient’s cough, which will typically last 10 to 14 days. Convey a sense of partnership and develop a symptom-based treatment plan with the patient (or caregiver) that describes the expected course of the illness over time with instructions to return if symptoms persist or worsen.

• Refer to the illness as a “chest cold” rather than bronchitis. Studies indicate that the term “chest cold” is less associated with antibiotic therapy.

• Personalize the risk of unnecessary antibiotic use. Antibiotics commonly have harmful side effects (gastrointestinal symptoms, taste alterations) and more rarely, adverse drug reactions. Previous antibiotic use increases the likelihood of carriage and infection with antibiotic-resistant bacteria.

• Explain that the current epidemic of antibiotic resistance among community bacterial pathogens is a major public health concern.

• Prescribe analgesics, decongestants and/or other symptom-based therapies, as appropriate.

• Emphasize the importance of adequate hydration and nutrition.

• Consider providing “care packages” containing nonantibiotic therapies.
**Bronchitis, Acute**

**Treatment for Adults**

Recommendation applies to immunocompetent adults without complicating comorbid conditions such as chronic lung or heart disease (e.g., > 65 years, COPD, CHF).

In presumptive diagnosis of bronchitis, focus on ruling out serious illness, particularly pneumonia in healthy, non-elderly patient with acute (< 3 weeks) cough with or without phlegm.

**Vital Signs**
- Screening for possible pneumonia - are any presenting?
  - Heart rate ≥ 100 beats/minute
  - Respiratory rate ≥ 24 breaths/minute
  - Body temperature ≥ 38°C (100.5°F)

If any of these signs are present, consider further evaluation.

**Chest x-ray to diagnose pneumonia**
- Yes
  - Pneumonia on CXR
    - Yes
      - Refer to Community Acquired Pneumonia guideline.
    - No
      - Consider anti-influenza therapy for symptoms < 48 hours duration.

- No
  - Chest exam suggests focal consolidation (e.g., rales, egophony or fremitus)
    - Yes
      - Begin treatment for bronchitis. Antibiotics not recommended regardless of cough duration.
        - Provide symptomatic relief/supportive care: Increased fluids, vaporizer
        - Dextromethorphan or codeine (cough > 3 weeks)
        - Bronchodilators (albuterol MDI)
        - Analgesics (NSAID, acetaminophen)
    - No
      - Is influenza likely?
        - Yes
          - Winter season with influenza in community
            - Upper respiratory tract symptoms, fever, abnormal vital signs
              - Consider anti-influenza therapy for symptoms < 48 hours duration.
        - No
          - Refer to Community Acquired Pneumonia guideline.
Introduction
Community acquired pneumonia (CAP) is an acute infection of the lung parenchyma associated with significant morbidity and mortality. CAP is characterized by acute signs and symptoms of infection and may include the presence of an acute infiltrate on chest radiograph or auscultory findings (such as altered breath sounds and/or localized rales) consistent with pneumonia.

Goals/Desired Outcomes
The goals of this CAP guideline are to reduce morbidity and mortality from CAP. Outcomes may be measured by a reduction in hospitalization, length of hospital stay, and adherence to the recommendations of these guidelines.

Diagnosis
Patients presenting with CAP may have fever or hypothermia, rigors, sweats, new cough (with or without mucous production) or change in color or texture of the sputum in patients with chronic cough, onset of dyspnea, or chest discomfort. Patients rarely have fewer than two of the preceding symptoms. Patients with signs and symptoms of pneumonia should generally have a chest radiograph performed. It is not necessary for patients without a localized finding in a physical exam and viral symptoms to get a chest x-ray. To avoid the unnecessary use of antibiotics, appropriate diagnosis is essential. Blood cultures and a sputum gram stain are recommended for hospitalized patients and selected non-hospitalized patients. Seriously ill patients should also have arterial blood gases or oximetry reading, BUN, serum sodium, glucose and hematocrit testing to assist in determining level of care and appropriateness of hospitalization.

Guideline Summary
- CAP patients present with fever or hypothermia, rigors, sweats, new cough with or without sputum production or change in the color of respiratory secretion in a patient with chronic cough, chest discomfort, or onset of dyspnea.
- Chest x-ray should be obtained in patients with signs and symptoms of CAP and all patients when hospitalization is a consideration.
- Patients with high fever (≥40°C), increased pulse rate (>125/min), increased respiratory rate (>30/min) decreased O2 sat (<92%), alteration in mental status, serious comorbid conditions or advanced age should be carefully evaluated for hospitalization. (Consider using PORT scoring to establish risk).
- The majority of CAP patients can be safely treated in the outpatient setting with macrolides, fluoroquinolones and doxycycline.
- Duration of antibiotic therapy is dictated by the presumed etiologic agent and the patient’s clinical course. The course should be from seven days to two weeks in most cases. I.V. antibiotics may be required as initial inpatient therapy, but may be changed to oral in most patients when they have a clearing response.

REFERENCE

WEBSITE
http://www.icsi.org

GUIDELINE DATE
November 18, 2003
Community-Acquired Pneumonia
Treatment for Adults

Step 1: Lowest Severity Level

- Age ≤ 50 years
- No significant comorbid conditions
- Normal or mildly damaged vital signs
- Normal mental status

Initial Risk Reduction

Patients with community-acquired pneumonia

Is the patient over 50 years of age?

Yes

Assign patient to risk class II-V* based on Pneumonia Severity Index score.

No

Does the patient have a history of any of the following comorbid conditions?
- Neoplastic disease
- Congestive heart failure
- Cerebrovascular disease
- Renal disease
- Liver disease
- Type 2 Diabetes Mellitus

Yes

No

Assign patient to risk class I*

Does the patient have a history of any of the following abnormalities on physical examination?
- Altered mental status
- Pulse ≥ 125/min
- Respiratory rate ≥ 30/min
- Systolic BP < 90 mm Hg
- Temperature < 35 °C or ≥ 40 °C

Yes

No

* See Risk Level Scoring, page 14-5
Community-Acquired Pneumonia
Treatment for Adults

Treatment

The decision to hospitalize a patient should take into account age, comorbid conditions, and severity of illness at the time of presentation. Inappropriate admissions of a patient may lead to the potential for a more serious secondary infection.

The antibiotic classes macrolides, fluoroquinolones, and doxycyclines are recommended for outpatient treatment. Macrolides are favored for the younger patient (under 40) to cover the atypical pneumonias more common in this age group. A beta-lactam agent with good antipneumococcal coverage (cefuroxime, amoxicillin, or amoxicillin-clavulanate) is recommended when the clinical setting or laboratory tests indicate an acute bacterial infection.

In-patient therapy is directed toward the specific etiologic agent when known. Empiric therapy includes coverage for atypical pneumonia plus a beta-lactam agent. Multiple antibiotics with broad coverage are recommended for the severely ill patient. The recommended duration of therapy is at least seven days, with 10 to 14 days for more severely ill patients.

Step 2—Algorithm Key (see next page)

<table>
<thead>
<tr>
<th>Pneumonia Severity Index</th>
<th>Points Assigneda</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demographic Factor</strong></td>
<td></td>
</tr>
<tr>
<td>Age (in years)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>actual age</td>
</tr>
<tr>
<td>Female</td>
<td>age -10</td>
</tr>
<tr>
<td>Nursing Home Resident</td>
<td>age +10</td>
</tr>
<tr>
<td><strong>Comorbid Illness</strong></td>
<td></td>
</tr>
<tr>
<td>Neoplastic Diseaseb</td>
<td>+30</td>
</tr>
<tr>
<td>Liver Diseasec</td>
<td>+20</td>
</tr>
<tr>
<td>Congestive Heart Failured</td>
<td>+10</td>
</tr>
<tr>
<td>Cardiovascular Diseaseg</td>
<td>+10</td>
</tr>
<tr>
<td>Renal Diseaseh</td>
<td>+10</td>
</tr>
<tr>
<td><strong>Physician Examination Finding</strong></td>
<td></td>
</tr>
<tr>
<td>Altered Mental Stateg</td>
<td>+20</td>
</tr>
<tr>
<td>Resp. Rate &gt;30 breaths/min.</td>
<td>+20</td>
</tr>
<tr>
<td>Systolic BP &lt;90 mmHg</td>
<td>+20</td>
</tr>
<tr>
<td>Temperature &lt;35 C or &gt;40 C</td>
<td>+15</td>
</tr>
<tr>
<td>Pulse &gt;125 beats/min.</td>
<td>+10</td>
</tr>
<tr>
<td><strong>Lab or radiographic finding</strong></td>
<td></td>
</tr>
<tr>
<td>Arterial pH &lt;7.35</td>
<td>+30</td>
</tr>
<tr>
<td>BUN &gt;30 mg/dL</td>
<td>+20</td>
</tr>
<tr>
<td>Na &lt;130 mEq/L</td>
<td>+20</td>
</tr>
<tr>
<td>Glucose &gt;250 mg/dL</td>
<td>+10</td>
</tr>
<tr>
<td>Hematocrit &lt;30%</td>
<td>+10</td>
</tr>
<tr>
<td>Arterial PO2 &lt;60 mmHg</td>
<td>+10</td>
</tr>
<tr>
<td>Pleural effusion</td>
<td>+10</td>
</tr>
</tbody>
</table>

a A total point score for a given patient is obtained by adding the patient’s age in years (age 21 for females) and the points for each applicable patient characteristic. Points assigned to each predictor variable were based on coefficients obtained from the logistic regression model used in step 2 of the prediction rule.

b Any cancer except basal or squamous cell cancer of the skin that was active at the time of presentation or diagnosed within one year of presentation.

c A clinical or histologic diagnosis of cirrhosis or other form of chronic liver disease such as chronic active hepatitis.

d Systolic or diastolic ventricular dysfunction documented by history and physical examination, as well as chest radiography, echocardiography, MUGA scanning, or left ventriculography.

e A clinical diagnosis of stroke, transient ischemic attack, or stroke documented by MRI or computed axial tomography.

f A history of chronic renal disease or abnormal blood urea nitrogen and creatinine values documented in the medical record.

g Disorientation (to person, place, or time, not known to be chronic), stupor, or coma.

h In the Pneumonia Patient Outcome Research Team cohort study, an oxygen saturation value <90% on pulse oximetry or intubation before admission was also considered abnormal.
Community-Acquired Pneumonia

Evaluation for community acquired pneumonia
- Hx of cough and other symptoms of lower respiratory tract infections
- Take vital signs

Screening for possible pneumonia—are any of the following present?
- Heart rate > 100 beats per minute
- Respiratory rate > 24 breaths per minute
- Body temperature > 38º C (100.5º F)

Chest exam suggests focal consolidation? (e.g. rales, egophony, fremitus)

Chest X-ray to diagnose pneumonia

Compatible clinical features supporting diagnosis of pneumonia?

Score > 90
Evaluate for admission using pneumonia PORT scoring *
Score 71-90
Tight Outpatient Management or Brief Inpatient
Score ≤ 70
Hospitalize patient

Consider alternate diagnosis (e.g., acute bronchitis, influenza)

Strong Consideration for Outpatient Management
- Obtain sputum for staining (optional)
- Empiric therapy with macrolide, doxycycline, or fluoroquinolone

*Pneumonia PORT scoring
## Community-Acquired Pneumonia
### Treatment for Adults

**Risk Level Scoring (use with Treatment Algorithm on page 14-4)**

<table>
<thead>
<tr>
<th>Risk Level</th>
<th>30-Day Mortality</th>
<th>Risk Class</th>
<th>Based On</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>&lt;0.5 percent</td>
<td>I</td>
<td>Algorithm</td>
</tr>
<tr>
<td>Low</td>
<td>≥0.5 and &lt; 1.0 percent</td>
<td>II</td>
<td>70 or fewer points</td>
</tr>
<tr>
<td>Low</td>
<td>≥1.0 and &lt; 4.0 percent</td>
<td>III</td>
<td>71-90 points</td>
</tr>
<tr>
<td>Moderate</td>
<td>≥4.0 and &lt; 10.0 percent</td>
<td>IV</td>
<td>91-130 points</td>
</tr>
<tr>
<td>High</td>
<td>≥10 percent</td>
<td>V</td>
<td>&gt; 130 points</td>
</tr>
</tbody>
</table>

Introduction
Acute pharyngitis accounts for one to two percent of all outpatient, office and emergency visits. While a wide range of infectious agents produces acute pharyngitis, viruses are the most common cause. In the vast majority of cases, acute pharyngitis in an otherwise healthy adult is self-limited and rarely produces significant sequelae. Approximately 10 percent of adult cases are caused by Group A β-hemolytic streptococcus (GABHS), and these patients should benefit from antimicrobial therapy.

Goals/Desired Outcomes
The goal of diagnostic evaluation is to distinguish patients with GABHS pharyngitis and make appropriate antibiotic treatment decisions. Treatment guidelines in this section apply to immunocompetent adults with no history of rheumatic fever and without complicated comorbid conditions such as chronic lung or heart disease. The guidelines do not apply during known outbreaks of Group A streptococcus.

• Provide supportive care to the large majority of adults with acute pharyngitis who have a self-limited illness.
• Provide antibiotic treatment for pharyngitis only for adult patients with GABHS infection. Gonococcal pharyngitis and diphtheria are appropriate for immediate antibiotic treatment and are excluded from discussion in this guideline.
• Offer patients with pharyngitis appropriate doses of analgesics and antipyretics, as well as other supportive care (e.g., gargles).

Diagnosis
Do not use throat culture to diagnose GABHS in an otherwise healthy adult. Other reasonably accurate approaches allow treatment decisions to be made earlier in the course of illness, when patients can receive symptomatic benefit. A clinical screening, including history and physical examination, would identify most patients with GABHS while dramatically decreasing excess antibiotic use.

The most reliable predictors of GABHS pharyngitis are the Centor criteria, which include history of fever, tonsillar exudates, absence of cough, and tender anterior cervical lymphadenopathy. Several studies examining these four criteria in clinical decision-making indicate that in patients who have three or four of the criteria, both the sensitivity and specificity associated with use of the criteria (compared with those of throat culture) are approximately 75 percent.

Rapid antigen tests for GABHS, when compared to throat culture, have widely variable sensitivity and specificity, depending on the type of test and practice setting. Practitioners should consider the economic costs of a few extra prescriptions versus the costs of many extra rapid antigen tests.
Pharyngitis, Acute

Guideline Summary (continued)

• Rapid antigen test should be performed only when 2 or 3 Centor criteria are met.
• Limit antibiotics to patients with positive results.
• For patients with 3-4 Centor criteria, use antibiotic therapy.
• For GABHS, penicillin therapy is first choice for patients without penicillin allergy.

It is recommended that rapid antigen tests be performed only in patients with an intermediate clinical probability of GABHS (those with two or three of the four clinical variables), and that antimicrobial agents not be prescribed when test results are negative.

Following are recommended diagnostic procedures:

• Clinically screen all adult patients with pharyngitis for the presence of the four Centor criteria: 1) history of fever, 2) tonsillar exudates, 3) no cough, and 4) tender anterior cervical lymphadenopathy (lymphadenitis).
• Do not test or treat patients who meet one or none of the Centor criteria; such patients are unlikely to have GABHS infections.
• For patients who meet two or three criteria, the following approach is appropriate:
  - Test patients by using rapid antigen test.
  - Limit antibiotic therapy to patients with positive results.
• For patients who meet three or four criteria, the following approach is appropriate:
  - Do not perform diagnostic tests.
  - Use antibiotic therapy.
• Do not perform throat culture for the routine primary evaluation of adults with pharyngitis or for confirmation of negative rapid antigen tests when the test sensitivity exceeds 80 percent.
Pharyngitis, Acute

Treatment for Adults

Treatment

Antimicrobial treatment of GABHS pharyngitis leads to a decreased risk of already rare complications and a decrease in the duration of some patient symptoms by one or two days. Begin treatment within 48 to 72 hours of symptom onset. For otherwise healthy adult patients with GABHS pharyngitis who have an aversion to antimicrobial agents or medications, it is reasonable to provide no antimicrobial treatment and expect few measurable adverse consequences. An appropriate strategy is to limit antimicrobial therapy to the minority of adults who are most likely to benefit from the therapy, such as those with a high likelihood of GABHS pharyngitis.

- Administer appropriate analgesics (topical and systemic), antipyretics and supportive care (e.g., gargles) to all patients with pharyngitis. The overwhelming majority of adults with acute pharyngitis have self-limited illness, which responds well to supportive care only.
- Physicians should limit antimicrobial prescriptions to patients who are most likely to have GABHS. GABHS is the causal agent in 10 percent of adult cases of pharyngitis and antibiotic efficacy is limited to these patients. Either of the following treatment approaches is appropriate:
  - Provide empirical antibiotic treatment in adults with at least three of four clinical criteria shown to be associated with GABHS. Do not treat all others.
  - Provide empirical treatment of adults with all four clinical criteria. Conduct rapid antigen testing of patients with two or three clinical criteria, followed by treatment of those with positive test results. Do not treat all others.
- Choose an antimicrobial agent with the narrowest possible spectrum of action that still covers GABHS. Penicillin is the first choice for patients without penicillin allergy; erythromycin is the first choice for penicillin-allergic patients. To date, there is no evidence of GABHS resistance to penicillin, and erythromycin resistance rates are low in the United States.

Guideline Summary (continued)

- Erythromycin is the first choice for penicillin-allergic patients.
- Acute pharyngitis in healthy adults is usually self-limited and rarely produces sequelae.
- Treatment includes appropriate analgesics, antipyretics and supportive care.
Group A β-hemolytic streptococcus (GABHS) infection

History and Screening (Centor criteria) in otherwise healthy patient
- History of fever
- Tonsillar exudates
- No cough
- Tender anterior cervical lymphadenopathy (lymphadenitis)

Number of screening criteria present
- 0 or 1: Low probability of GABHS; testing not advised.
- 3 or 4: High probability of GABHS infection; rapid antigen test unnecessary.
- 2 or 3: Rapid antigen test

Test result positive?

No
- Antibiotics not recommended. Offer patient symptom relief and supportive care: analgesics, antipyretics, gargles.

Yes
- Limit antibiotics to GABHS-positive patients. Preferred agent: narrow-spectrum antibiotics, e.g., penicillin, or erythromycin in penicillin-allergic patients. Provide symptomatic treatment and supportive care.
Introduction
Sinusitis refers to inflammation of the mucosa of the paranasal sinuses. Because it is invariably accompanied by inflamed contiguous mucosa, sinusitis is more appropriately referred to as rhinosinusitis. Rhinosinusitis is one of the 10 most common diagnoses in ambulatory practice, and the fifth most common diagnosis for which antibiotics are prescribed. Primary care physicians tend to treat this as an acute bacterial infection and prescribe an antibiotic more than 85 percent of the time. However, rhinosinusitis is frequently a viral infection, and even if bacterial in origin, will often resolve in most patients without antibiotic treatment.

Goals/Desired Outcomes
These recommendations apply to immunocompetent adults without complicating comorbid conditions, such as chronic lung or heart disease.

• Acute rhinosinusitis, whether bacterial or viral, does not usually require antibiotic treatment, especially if symptoms are mild or moderate.
• Treat patients with severe or persistent moderate symptoms and specific findings of bacterial rhinosinusitis with antibiotics. Narrow-spectrum antibiotics are reasonable first-line agents.
• Sinus radiography is not recommended for the diagnosis of uncomplicated sinusitis.

Diagnosis
The symptoms of acute rhinosinusitis lack specific clinical features to distinguish it from nonbacterial upper respiratory tract infections. Rhinovirus illnesses are common and usually last from one to 33 days. Most patients will be well or nearly well in seven to 10 days. However, 25 percent will still be symptomatic after 14 days. Bacterial sinusitis is not common in patients whose symptoms have lasted less than seven days. Therefore, the presence of symptoms for at least seven days is a moderately sensitive but nonspecific predictor of bacterial rhinosinusitis. Purulent nasal discharge, maxillary tooth or facial pain (especially when unilateral), unilateral sinus tenderness, and worsening of symptoms appear to predict bacterial infection.

Treatment
• Provide symptomatic treatment and reassurance (the preferred initial management strategy for patients with mild symptoms).
• Do not use sinus radiography for diagnosis in routine cases.
• Reserve antibiotic therapy for patients with severe symptoms who meet the criteria for the clinical diagnosis of acute bacterial rhinosinusitis, regardless of duration of illness.

REFERENCE

WEBSITE

GUIDELINE DATE
November 18, 2003

Guideline Summary
• Guideline applies to immunocompetent adults.
• Rhinosinusitis is frequently a viral infection
• Bacterial sinusitis is not common in patients whose symptoms last < 7 days
• Symptoms of bacterial sinusitis include:
  - purulent nasal discharge along with maxillary tooth or facial pain (especially when unilateral)
  - unilateral sinus tenderness
  - worsening symptoms
• Clinical trials, amoxicillin, doxycycline or trimethoprim-sulfamethoxazole are favored antibiotics
Use narrow-spectrum agents when providing initial antibiotic treatment. Clinical trials suggest that amoxicillin, doxycycline and trimethoprim-sulfamethoxazole are the preferred antibiotics.

Patient Education and Satisfaction

Many patients expect to receive a prescription as treatment for the “common cold” (viral infections). However, obtaining an antibiotic prescription is not always correlated with increased patient satisfaction. Hamm et al reported patient satisfaction immediately after a visit was most highly related to patients’ reports of how much time the physician spent explaining the illness, and their understanding of the physician’s choice of treatment, and not to the physician’s prescribing antibiotics.

The physician may feel a duty to treat the patient presenting with a mild but uncomfortable illness with antibiotics, even if the likelihood of improving the outcome is small. Although antibiotics may offer little direct benefit, the physician may perceive even an insignificant clinical benefit as worth the economic cost to the patient. Potential adverse drug reactions, the association between antibiotic overuse, the development of resistant organisms, and the expense of antibiotics are compelling reasons for prescribing them only when necessary.

When patients ask for antibiotics to treat a viral upper respiratory infection (VURI), discussions may include the following:

- Antibiotics are appropriately prescribed for bacterial infections, not viral infections. Treating viral infections with antibiotics is not effective and does not serve as a preventive measure against bacterial infection.
- Unnecessary antibiotics can be harmful (e.g., may cause adverse drug reactions). The latest evidence indicates that unnecessary antibiotics promote resistant organisms in the patient and the community.
- Build trust; do not minimize the illness as “only a viral infection.”
- Convey a sense of partnership. Develop a symptomatic treatment plan with the patient (or caregiver) that describes the expected course of the illness over time with instructions to return if symptoms persist or worsen.
- Prescribe analgesics, decongestants and/or other symptom-based therapies, if appropriate. Emphasize the importance of adequate hydration and nutrition, and consider providing “care packages” containing nonantibiotic therapies.
Rhinocinutis, Acute

Treatment Algorithm

Focused H&P for acute rhinosinusitis:
- Duration of symptoms
- Fever
- Amount and consistency of nasal discharge
- Pain or discomfort
- Progression of symptoms
- Associated symptoms
- Comorbid conditions

Symptoms of bacterial infection
Should have most or all of the following:
- Symptoms > 7 days
- Fever
- Purulent nasal discharge
- Persistent or progressive maxillary tooth/facial pain (particularly unilateral sinus tenderness)

Initial antibiotic treatment
Choose narrow-spectrum agents:
- amoxicillin
- doxycycline
- trimethoprim-sulfamethoxazole

Symptom relief (OTC)
Patient education

Patient self-monitoring of outcome
If necessary, physician re-evaluates for persistent symptoms (e.g., >3 weeks progressive symptoms).

Recommendation applies to immunocompetent adults without complicating comorbid conditions such as chronic lung or heart disease (e.g., > 65 years, COPD, CHF).

Procedures not routinely recommended:
- Sinus radiography has demonstrated limited value in diagnosis.
- Repeat office visit follow-ups are not necessary in most cases.
- Lab work not routinely recommended.
Viral Upper Respiratory Infection
Treatment for Adults

Introduction
Upper respiratory tract infections (including the common cold) represent an important target for improving appropriate antibiotic use in ambulatory practice. In 1995, upper respiratory tract infection was the most common reason for seeking ambulatory care in the United States, resulting in more than 37 million visits to physicians' offices and emergency rooms. Antibiotics are frequently prescribed for upper respiratory tract infections.

Goals/Desired Outcomes
The goal of this guideline is to assist patients, through education, to be competent and comfortable with home care of viral upper respiratory infection (VURI), and to improve the appropriateness of care for VURIs while decreasing cost of care. This guideline aims to:
1. Increase the appropriateness of patient visits for VURI.
2. Eliminate inappropriate use of antibiotics in patients presenting with cold symptoms.
3. Increase patient knowledge of effective home treatment of cold symptoms.

Diagnosis
Patient will report various combinations of symptoms. The symptoms of VURI may include general malaise, laryngitis, injection of the conjunctivas, decreased appetite, headache, and restlessness. Onset of symptoms is rapid. The fever usually lasts one to three days and commonly does not exceed 102°F. Nasal discharge is initially clear and usually becomes yellow or green toward the end of the VURI; this does not signify a bacterial infection and the patient does not need to be seen. The symptoms of a VURI usually peak in three to five days and should resolve in seven to 14 days. A mild cough may persist at night for two to three weeks. Refer to Acute Pharyngitis guidelines for those patients reporting a sore throat without rhinorrhea, cough or hoarseness.

Are symptoms of serious illness present?
Recognizing the signs of a serious illness before it becomes life-threatening is usually the medical provider's key concern. An important purpose of Table 1 is to assist providers and triage personnel in distinguishing between VURI and more serious illness. The urgency index increases with the number and severity of symptoms. Symptoms in the Guideline Summary indicate which patients presenting with VURI symptoms need to be seen by a provider.

REFERENCE


WEBSITE
http://www.icsi.org/guide/VURI.pdf

GUIDELINE DATE
November 18, 2003

Guideline Summary
• This guideline applies to immunocompetent adults without complicating factors.
• Symptoms of VURI usually peak in three to five days and resolve in seven to 14 days.
• Refer to Acute Pharyngitis guidelines for patients with sore throat without rhinorrhea, cough or hoarseness.
• Recognizing signs of serious illness before it becomes life-threatening is a key concern.
Are complicating factors present?

- This guideline applies to patients in normal health and without complicating factors.
- This guideline should be applied with great care, if at all, to any patients with complicating factors.
- Although this guideline would be applied with caution to pregnant women, therapies recommended in this guideline are generally safe for pregnant women except for the use of zinc and dextromethorphan. Dextromethorphan is classified pregnancy category C (no controlled studies; give only if benefits outweigh risks).

Table 1: Symptoms of Serious Illness

<table>
<thead>
<tr>
<th>SYMPTOMS OF SERIOUS ILLNESS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Upper Airway Obstruction</strong></td>
</tr>
<tr>
<td>Peritonsillar or retropharyngeal abscesses, epiglottitis or related conditions are life-threatening and require combined ENT/anesthesia management in an emergency room or operating room setting.</td>
</tr>
<tr>
<td><strong>Lower Airway Obstruction</strong></td>
</tr>
<tr>
<td>Lower airway obstruction signals an underlying or different condition than VURI. If moderate to severe distress is present, this suggests pneumonia, COPD, asthma, foreign body, cardiac condition or other underlying conditions requiring specific evaluation and treatment in an intensive care setting. Such symptoms indicate the need for urgent evaluation, and/or the need for intensive treatment, supplemental oxygen, and prolonged observation.</td>
</tr>
<tr>
<td><strong>Severe Headache</strong></td>
</tr>
<tr>
<td>Severe headache could indicate subarachnoid hemorrhage; complications of sinusitis such as cavernous sinus thrombosis or sphenoid sinusitis; meningitis, encephalitis, or other conditions. Such symptoms require prompt, intensive evaluation and care.</td>
</tr>
</tbody>
</table>
Treatment

Antibiotics
- Antibiotics are only effective for treating bacterial infections. Because colds are viral infections, antibiotic use will not cure or shorten their duration.
- Antibiotics may cause side effects such as gastrointestinal discomfort, diarrhea, allergic reactions, and yeast infections.
- Unnecessary use of antibiotics can lead to the development of antibiotic-resistant strains of bacteria.

Over-the-counter medications
- Over-the-counter cold and cough medications and acetaminophen do not shorten the duration of VURI.
- For adults with a cold, over-the-counter nasal sprays or decongestants may provide temporary relief of sore throat, runny nose, coughing, minor aches and fever. Because of potential side effects, however, be sure to follow the recommended dosage and precautions. Patients who have high blood pressure, diabetes, thyroid disease, or are pregnant, should check with their physician regarding recommendations for decongestant use.
- Fevers that accompany colds are usually less than 102°F and last less than three days. Use medication for discomfort as recommended by a physician.
- In adults, there is some evidence that zinc gluconate may decrease the duration of a cold if started within 24 hours of onset. However, adverse reactions including nausea and bad taste may limit its usefulness. No current studies indicate zinc is effective in treating cold symptoms in children.

Treatment Summary

- Antibiotics will not shorten or cure VURI.
- OTC nasal sprays or decongestants may provide temporary relief of VURI symptoms.
- Cold-related fevers are usually less than 102°F and last < 3 days.
**Routine Antepartum Guidelines**

### Initial Antepartum Visit
- Patient OB history
- Physical exam
- Initial labs
- Education and counseling

### Visit Schedule
- **Initial Visit**
  - Establish surveillance and obstetric record
  - LMP, OB history, medical history, nutritional history, EDC, social history, physical exam.
- **Patient education and information**
  - Counseling on nutrition, physical activity, smoking, ETOH, drugs, travel, cats, sex, exercise, domestic violence, breastfeeding.
  - Literature on available birthing classes.
  - Birthing plan and birthing center orientation.
  - Prebirth selection of and contact with a pediatrician.
- **Risk assessment and care plan**
  - Maternal medical problems, family history, specific obstetric problems (e.g., signs and symptoms of preterm labor, pregnancy-induced hypertension, etc.), genetic problems, social/financial problems.
  - Offer influenza vaccination of 2nd or 3rd trimester in flu season.

- **Initial Labs**
  - DM screening for high-risk patients
  - Hemoglobin or hematocrit
  - Complete urinalysis with culture
  - Blood group and Rh type
  - Antibody screening
  - Rubella antibody titer
  - Cervical cytology
  - Hepatitis B screening
  - HIV screening (patient consent required)
  - Syphilis screening
  - Strong consideration to screen for chlamydia and gonorrhea in all patients

- **Routine Visit**
  - Interval history
  - Blood pressure
  - Weight
  - Uterine size
  - Fetal heart rate
  - Urine protein
  - Urine glucose
  - Assessment and education

- **Visit Schedule**
  - 4-28 Weeks Q4W
  - 28-36 Weeks Q2-3W
  - 36-40+ Weeks Q1W
  - or more often as clinically needed

### 8-18 Weeks
- Ultrasound
- Amniocentesis or Chorionic Villus Sampling (high-risk patients)
- Cystic fibrosis screening (high-risk patients)
- TB testing
- Diabetes screening
  - (DM screening should be done 18-22 weeks for high-risk patients)

### 15-20 Weeks
- Triple Screen (ideally 16 weeks)

### 24-28 Weeks
- Hemoglobin or hematocrit
- Rh antibody screening & RhoGAM administration (at-risk patients)

### 32-36 Weeks
- Hemoglobin or Hematocrit
- Ultrasound
- Antepartum fetal testing
- Testing for STDs (high-risk patients)

### 35-37 Weeks
- Group B Strep screening

**REFERENCES**
- 2 Use of service based on patient’s clinical status and physician’s judgment.
Introduction

Depression and associated anxiety/depression disorders are underdiagnosed by primary care physicians and medical specialists. Even with appropriate diagnosis, inappropriate or inadequate medications are frequently prescribed. Primary care physicians see the majority of patients with depression and often maintain an ongoing clinical relationship with the patient even when the patient has psychiatric support. The following clinical guidelines are designed to provide a structured approach to the identification of patients with depression and mixed anxiety/depression in the primary care setting.

Diagnosis

The U.S. Preventive Services Task Force (USPSTF) now finds sufficient evidence to encourage primary care clinicians to screen their adult patients for depression. According to Task Force Chairman Dr. Alfred Berg, Chair of the Department of Family Medicine, University of Washington, Seattle, “Our panel found that asking two simple questions—over the past two weeks, have you ever felt down, depressed, or hopeless, and have you felt little interest or pleasure in doing things—may be as effective as using longer screening instruments.” An affirmative response to these questions may indicate the need for the use of more in-depth diagnostic tools.

The diagnosis of depression in the primary care setting is often associated with other conditions or symptoms that mask the diagnosis unless clinically pursued. The patient with symptoms of depression or unexplained weight gain or loss requires a careful history to establish the diagnosis of depression. Equally important is a careful clinical assessment of comorbidities and medication use that may play a role in the diagnosis or treatment. External social and economic forces may also add a significant component to the symptoms and further complicate the treatment.

If presenting symptoms are still mild but represent incomplete recovery from a prior full episode of depression, treat aggressively, including medication; move to the “Moderate to Severe Symptoms” arm of the Treatment of Depression algorithm in this section. Incomplete recovery is a high-risk factor for recurrence.

History

The history should include an evaluation of the patient’s medical condition, medication use, alcohol and drug use, somatic symptoms, psychiatric history, previous treatments and current social/economic situation. In addition, the diagnosis is established by specifically meeting the criteria covered in these guidelines and addressing or factoring in potential comorbid conditions that might account for the symptoms.

References


The ICSI Health Care Guideline: Major Depression in Adults for Mental Health Care Providers


Website

http://www.icsi.org
http://cme.med.umich.edu/pdf/guideline/depression.pdf

Guideline Date

November 18, 2003

Treatment Summary

• The USPSTF recommends screening adults for depression.

• Primary care clinicians should ask two simple questions:
  – Over the past two weeks, have you ever felt down, depressed, or hopeless?
  – Have you felt little interest or pleasure in doing things?
Diagnosis and Treatment in the Primary Care Setting

Depression

Medical conditions
Chronic medical conditions, particularly those associated with elements of functional disability, are associated with symptoms of depression. The effective treatment of these conditions often results in marked improvement or resolution of the symptoms of depression and is an essential component of the management of depression in patients with comorbid conditions.

Somatization
Patients often present with bodily complaints that fail to correspond with recognized physiologic pathology and may be psychosomatic in nature. These patients often are depressed and pose a challenging problem in diagnosis and treatment, as they are resistant to seeking psychiatric care and can resist trials with any psychiatric medication when their principal concern is with physical complaints.

Alcohol and substance abuse
Patients with a history of alcohol and substance abuse frequently have symptoms of depression and often also have complex social/economic problems that further complicate both diagnosis and treatment. Addressing both the substance abuse and depression concomitantly is crucial, and co-management with a mental health or substance abuse specialist is recommended. Specific attention to and the assessment of patients on chronic prescriptions for narcotics, sedative hypnotics or benzodiazepines is advised.

Medications
Several medications cause side effects consistent with depression or exacerbate symptoms of depression. Whenever possible, these medications should be stopped or reduced prior to pharmacological intervention for depression. Please refer to the Antidepressant Summary Chart in this section.

Warnings
- Some antidepressants have significant drug interaction. Please refer to package insert for each specific drug warning.
- Antidepressants occasionally trigger mania. Treatment emergent symptoms of agitation, anger, insomnia, and/or suicidal preoccupation require urgent psychiatric referral.

Psychiatric conditions
Patients with other preexisting or concurrent psychiatric conditions present complex cases that are best referred or comanaged with a psychiatric team.

Adherence
Patients with depression have additional barriers to medication adherence, such as depressive symptomatology (hopelessness and lack of motivation), side effects of medication, and stigma associated with a behavioral health illness. Therefore, medication adherence is a very impor-
tant element in depression treatment. An estimated 25 percent of patients misinform their physician about compliance, so it is important to address this topic as a separate and important part of the physician-patient interaction. Five messages specifically have been associated with adherence to antidepressant medication:

1. Take the medication daily.
2. Antidepressants must be taken for two to four weeks for a noticeable effect and continued for 6-9 months for full effect.
3. Continue to take medicine even if feeling better.
4. Do not stop taking antidepressant without checking with the physician.
5. Give specific instructions regarding what to do to resolve questions regarding antidepressants.

Specific instructions are particularly important as concrete suggestions have been found to increase medication adherence more than broad-based messages. Specific instructions could include as examples:

- Event-based medication consumption (such as tying to an event like a meal rather than a time of day)
- Self monitoring tools (such as pill boxes)
- Cues (such as reminders in bathroom or kitchen)
- What to do if a dose is missed
- Planning for extended time away from home

It is helpful to address medication adherence and reinforce the educational messages at each patient visit.

Medication Summary

- Take medication regularly as directed
- If effective, continue at least 6 months


2Patient education is mentioned on page 10 of the ICSI guideline and page 8 of the University of Michigan guideline.
**Depression Diagnosis Algorithm**

**Patient with possible depression/anxiety**
Ask the following questions:
- Over the past two weeks, have you ever felt down, depressed, or hopeless?
- Have you felt little interest or pleasure in doing things?

**History**
- Evaluate comorbid disease.
- Assess current medications and potential drug side effects.
- Evaluate for alcoholism and/or substance abuse.

**Anxiety**
Excessive anxiety and worries about a number of events occurring most days for at least six months and associated with at least three symptoms, including:
- Restlessness
- Easily fatigued
- Difficulty concentrating
- Sleep disturbance
- Irritability
- Muscle tension

**Depression**
Symptoms for > two weeks
One of the following:
- Depressed mood most of day, nearly every day
- Marked diminished interest/pleasure in activities most of the day, nearly every day
And any four of the following:
- Significant weight loss/gain
- Insomnia/hypersomnia
- Psychomotor agitation
- Fatigue (loss of energy)
- Feeling of worthlessness/guilt
- Impaired concentration (indecision)
- Recurrent thoughts of death/suicide

**Common comorbid diseases**
- Congestive heart failure
- Hyper/hypothyroid (particularly in elderly)
- Cancer
- COPD/emphysema
- Poorly controlled diabetes
- Parkinsonism
- Chronic infection
- Psychosomatic disorders
- Chronic arthritic conditions

**Urgent to emergent if patient or others are in danger of harm or death: comanage with psychiatrist and/or mental health professional**

**Comanage with mental health or substance abuse specialist if appropriate**

**Treat medical problems and attempt to reduce medications that may cause symptoms**

**Patient with alcohol or substance abuse**

**Coexisting medical condition or medication that may cause or complicate depression**

**See Treatment Algorithm**
Depression
Treatment Algorithm

**Moderate to severe symptoms**
- Chronic
- Limited situational stress

**Supportive counseling plus medication**
- Venlafaxine XR (Effexor XR)
- Lexapro
- Citalopram (Celexa)
- Sertraline (Zoloft)
- Fluoxetine (generic, Prozac)
- Paroxetine (Paxil, Paxil CR)
- Other

If anxiety persists, consider adding short-term anxiolytic.

**Insomnia prominent**
- Citalopram (Celexa)
- Lexapro
- Sertraline (Zoloft)
- Paroxetine (Paxil, Paxil CR)
- Other

Consider adding trazodone if insomnia persists

**Venlafaxine XR (Effexor XR)**
- Lexapro
- Citalopram (Celexa)
- Sertraline (Zoloft)
- Other

Continue treatment for up to 6 weeks. Evaluate in 2 weeks; check for side effects. Adjust dosage if necessary.

**History of SSRI induced sexual dysfunction**

**Antidepressants occasionally trigger mania. Treatment emergent symptoms of agitation, anger, insomnia, and/or suicidal suicidal preoccupation require urgent psychiatric referral.**

**Clinical remission**
- Yes
- Comanage with a psychiatrist or switch class of drugs.

**Recommended follow-up: 3 visits minimum in 12 weeks**

---

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*If a patient has had previous success with an antidepressant, including tricyclic antidepressants (TCA), use that medicine, if still appropriate.
# Depression: First-Line Antidepressants

## Table 2: Matching Antidepressants to Patients: Selection Criteria for First-Line Agents

<table>
<thead>
<tr>
<th>Serotonin Selective Reuptake Inhibition</th>
<th>Serotonin/Norepinephrine Reuptake Inhibition</th>
<th>Norepinephrine/Dopamine Reuptake Inhibition</th>
<th>Serotonin-2 Antagonist/Reuptake Inhibition</th>
</tr>
</thead>
<tbody>
<tr>
<td>paroxetine (Paxil)</td>
<td>Tricyclic Antidepressants (multiple)</td>
<td>venlafaxine (Effexor)</td>
<td>Trazodone (Desyrel)</td>
</tr>
<tr>
<td>sertraline (Zoloft)</td>
<td></td>
<td>bupropion (Wellbutrin)</td>
<td></td>
</tr>
<tr>
<td>fluoxetine (Prozac)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>citalopram (Celexa, Lexapro*)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Side effects used in patient selection
- Anticholinergic properties that tend to reduce arousal & insomnia
- 1-day half-life Linear blood concentration, not over usual dose range. No age effect on renal clearance.
- Very long half-life (7-15 days)
- Long half-life (35 hours)
- Sedation common. Dry mouth, urinary retention, orthostatic hypotension, weight gain, potential for arrhythmia & cardiac conduction disturbances.
- Identical to those common to all SSRIs with > nausea. 1 to 7.5mm Hg>BP for 3% of patients. Low protein binding and linear-dose response.
- Least likely to switch patient to mania. Most activating antidepressant available. DO NOT USE if hx of seizure disorder, head trauma, bulimia/anorexia.
- Corrects sleep disturbance reduces anxiety in ~1 wk. Side effects somewhat opposite to SSRIs. Understudied w/sever depression. Fatigue & dizziness common complaints.

### Sexual Disfunction
- Potential inhibitor of P450 2D6 enzyme
- Weakest SSRI inhibitor of P450 2D6 enzyme
- Weak inhibitor P450 2D6 enzyme
- Many drugs can affect TCA levels, carbamazepine, phenytoin, phenobarbital, rifamipin. TCAs may increase effects of warfarin.
- Usually clinically insignificant due to low protein binding.
- Complex bio-transformation is relatively unstudied. However, drug-drug interactions are uncommon.
- Potential terfenadine, astemizole, cisapride interactions.

### Selected important drug interactions
- Selected drug interactions include carbamazepine, tricyclic antidepressants, and warfarin.

### Patient profile most likely to benefit
- Once-a-day SSRI dosing desirable but want SSRI least likely to produce anxiety and/or insomnia
- The medical surgical patient on one or more medical drugs
- The young depressed patient with chronic pain
- The med/surg pt compliant with BID dosing (q d dosing for extended release) Patients failing an SSRI trial
- The depressed patient who has or may have bipolar disorder
- Over-anxious patients with marked difficulty sleeping

### Patient least likely to benefit
- Elderly or similar patient who might require high dose and, therefore be more prone to anticholinergic effects.
- Patient sensitive to any of the typical SSRI side-effects (e.g. increased arousal).
- Patient on several medications and/or frequent medication changes anticipated.
- Elderly patients. Any patient with conduction system disease (multiple side effects and danger in overdose make the TCAs difficult to use).
- Patients with unstable BP and, perhaps, those who are "GI" sensitive. A clinically significant withdrawal syndrome requires slow downtaper.
- Patients who are agitated, very anxious and/or panickly.
- Patients who sleep excessively with lifelong underachievement and excessive contentment. Patients with very severe depression.

---

1. It is the responsibility of the treating physician to be current with the psychopharmacology of antidepressants and to determine dosages and drug interactions, and the best treatment for the patient.
2. Developed by David J. Knesper, M.D., University of Michigan Department of Psychiatry.
3. Added by the HMSA Medical Advisory Committee
4. Bold face type is used in the following table to indicate medications that are preferred agents on the HMSA SELECT formulary and on formulary for HMSA QUEST.
5. (a) If a patient fails one class of antidepressants, another class should be tried.
6. (b) Do not combine any of the listed antidepressants with monoamine oxidase inhibitors (MAOIs)

---

*Lexapro is escitalopram, the S-enantiomer of racemic citalopram. Escitalopram is at least 100 times more potent than the R-isomer of citalopram. (The Medical Letter Vol 44 Num 1140).*
Medications in boldface type are preferred agents on the HMSA SELECT formulary and on the formulary for HMSA QUEST.

<table>
<thead>
<tr>
<th>Medication [Class]</th>
<th>bupropion SR (Wellbutrin SR) [NDRI]</th>
<th>Mirtazapine (Remeron) [NASSA]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Dose [Geriatric dose]</td>
<td>150 mg am</td>
<td>15 mg hs</td>
</tr>
<tr>
<td>Maximum Recommended Dose</td>
<td>Increase to 150 mg bid no sooner than four days after beginning therapy. After several weeks of treatment, increase in dosage may be considered up to 200 mg bid.</td>
<td>May increase to 45 mg/day by increments of 15 mg/day at intervals of one to two weeks.</td>
</tr>
<tr>
<td>Effect on Energy</td>
<td>Stimulating</td>
<td>Sedating</td>
</tr>
<tr>
<td>FDA Approved Indication(s)</td>
<td>Depression</td>
<td>Depression</td>
</tr>
<tr>
<td>Special Indications</td>
<td>• Augmentation for lethargic or anhedonic depression&lt;br&gt;• Sexual dysfunction (affects libido)&lt;br&gt;• Bipolar II (hypomanic)&lt;br&gt;• ADHD</td>
<td>• To avoid sexual dysfunction</td>
</tr>
<tr>
<td>Serious Side Effects</td>
<td>• Seizures (especially at &gt; 400 mg/day)&lt;br&gt;• MAOI [C]</td>
<td>• Agranulocytosis, neutropenia&lt;br&gt;• MAOI [C]</td>
</tr>
<tr>
<td>Precautions</td>
<td>• Seizure disorder [C]&lt;br&gt;• Bulimia/ anorexia [C]&lt;br&gt;• Decreased seizure threshold (BZD discont. anti-psychotics)&lt;br&gt;• Recent MI (arrhythmia)</td>
<td>• Recent MI&lt;br&gt;• Sedation&lt;br&gt;• Weight gain</td>
</tr>
</tbody>
</table>
## Depression

### Medication Summary

<table>
<thead>
<tr>
<th>Medication [Class]</th>
<th>buspirone (Buspar)</th>
<th>lorazepam (generic Ativan)</th>
<th>Trazodone (generic Desyrel) [SARI]</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Initial Dose</strong> [Geriatric dose]</td>
<td>7.5 mg bid</td>
<td>2–3 mg/day in divided doses [1–2 mg/day]</td>
<td>50 mg hs</td>
</tr>
<tr>
<td><strong>Maximum Recommended Dose</strong></td>
<td>May increase to 60 mg/day by increments of 5 mg/day, at intervals of 2–3 days, as needed.</td>
<td>Varies from 1–10 mg/day given in divided doses; with largest dose at bedtime – increase dosage gradually.</td>
<td>May increase to 150 mg hs.</td>
</tr>
<tr>
<td><strong>Effect on Energy</strong></td>
<td>N/A</td>
<td>Sedative</td>
<td>Sedating</td>
</tr>
<tr>
<td><strong>FDA Approved Indication(s)</strong></td>
<td>Anxiety</td>
<td>Anxiety</td>
<td>Depression</td>
</tr>
<tr>
<td><strong>Special Indications</strong></td>
<td>Chronic insomnia</td>
<td></td>
<td>• Insomnia</td>
</tr>
<tr>
<td><strong>Serious Side Effects</strong></td>
<td>• MAOI [C]</td>
<td>• Neutropenia • Hepatic dysfunction</td>
<td>• Priapism • Agranulocytosis, leukopenia</td>
</tr>
<tr>
<td><strong>Precautions</strong></td>
<td>• Sedation • Akathisia</td>
<td>• Psychoses [C] • Narrow-angle glaucoma [C] • Dependence • Caution in elderly</td>
<td>• Cardiac disease • Sedation</td>
</tr>
</tbody>
</table>
Introduction

Individuals have more than a 90% chance of experiencing headache in their lifetime.1 Surveys indicate that nearly 35% of adults in the U.S. annually report recurring episodes of severe headache, and 4% experience daily or near-daily headaches.2,4 Use of prescription or non-prescription products to treat headache is comparable to hypertension as the primary reason for medication use.5

Goals

Evidence-based guidelines aid in the design of an effective treatment program. Several strategies for both management and preventive therapy are presented below to maximize the potential for successful outcomes.

Diagnosis

The initial step in headache assessment requires screening for secondary origins. A thorough history combined with general and focused neurological examinations is mandatory. Neuroimaging procedures or analysis of serum or cerebrospinal fluid is required when one of the red flags of secondary headache presentations is encountered.6

Once secondary origins are excluded, primary headaches should be differentiated as episodic or chronic headache disorders. A chronic condition occurs when the attacks occur more frequently than 15 days per month for more than six months.7 With over 4% of adults in the U.S. reporting chronic daily headaches, most represent chronic forms of either migraine or tension-type headache.4

The majority of patients seen in a primary care setting will be experiencing episodic primary headache disorders.5,8 Traditional diagnosis is founded on a symptom-based paradigm initially developed by the IHS for purposes of clinical research. Significant symptom overlap between primary headache types has raised concerns about the clinical specificity of such a system.
Tension-type headache is the least distinct of the primary headache syndromes, and is defined by the absence of associated features. The pain is mild or moderate in intensity, generally bilateral, and non-pulsatile. Stress is listed as the most common trigger.

Episodic cluster headache is distinguished by its distinctive temporal pattern of grouped headache attacks recurring over several weeks or months. The episodes are characterized by minutes to hours of intense unilateral periorbital pain. Due to its low population prevalence, cluster headaches are also an infrequent consultation in primary care.

The characteristics of migraine attacks vary both among patients and among episodes with a single patient. Although the pain of migraine is typically considered to be unilateral and throbbing, 40% of sufferers may present with bilateral pain, and half with nonpulsatile pain. Recent data have also shown that 46% of migraineurs in a headache clinic setting describe cranial autonomic features, such as tearing or nasal congestion, symptoms often associated with sinus headache. Another study has shown that 75% of migraineurs report neck pain, a feature thought to be more typical of tension headache.

The variability of migraine pain, triggers, and associated features may help explain the underdiagnosis and misdiagnosis of migraine when the model used for headache diagnosis is symptom-based. As a result, alternative migraine recognition instruments have been proposed, using both pattern-based and impact-based recognition models. An instrument known as the Brief Headache Screen has been validated in a primary care setting as correlating well with IHS criteria for migraine, and the following modified four-question version of the screening test has been adopted by the American Academy of Neurology:

1. How often do you get severe headaches?
2. How often do you get other (milder) headaches?
3. How often do you take headache relievers or pain pills?
4. Has there been any change in your headaches over the past six months?

Secondary headaches are managed through treatment of the underlying pathology. A variety of headaches improve following triptan delivery, and response to treatment should not be used as a diagnostic tool for migraine or other primary headache conditions.

**Treatment**

**Acute Therapy**

Tension-type headache may be treated with nonpharmacological strategies such as relaxation training, stress management, and counseling. For frequent occurrences, a trial of a tricyclic or newer antidepressant is recommended. Acute attacks may be managed with simple or combination analgesics, limited to two to three days per week to avoid medication-overuse headache. For patients with chronic tension-type headache, a combination of amitriptyline hydrochloride and stress management proves more effective than either therapy alone.
Episodic cluster headaches can often be managed with short-term preventive agents such as corticosteroids or ergotamine tartrate during the initial two to four weeks. Long cluster episodes may require months of verapamil, methysergide, or lithium carbonate. First-line treatment of acute cluster headache is oxygen delivered at 7 to 12 L/min for 25 minutes. The only highly effective abortive agent is subcutaneous sumatriptan, with parenteral dihydroergotamine, intranasal sumatriptan, and intranasal lidocaine as alternatives.

Evidence-based guidelines are now available for nonpharmacological and pharmacological management of migraine headaches. Following a comprehensive review of all placebo-controlled trials, the U.S. Headache Consortium published evidence-based guidelines for acute and preventive therapies for migraine in a primary care setting. Clinical guidelines based on these publications have been adopted by the American Academy of Family Physicians and the American College of Physicians-American Society of Internal Medicine.

Designing an effective treatment program begins with profiling the headache condition and patient variables. Patients with frequent or extremely debilitating attacks are candidates for preventive therapy. Patients with rapidly developing pain, migraines upon awakening, or prominent gastrointestinal symptoms may warrant acute drug administration by nonoral routes. Patient variables to consider include age, sex, childbearing status, and medical conditions including hypertension and vascular disease. Conditions such as depression, anxiety disorders, irritable bowel syndrome, and epilepsy are comorbidities and should be considered when designing a treatment program.

The efficacy and tolerability of nonsteroidal anti-inflammatory drugs as first-line therapies for attacks is supported by evidence-based guidelines. Patients who do not respond on initial therapy to NSAIDs should proceed to migraine-specific therapies as soon as possible. Serotonin 1B/1D agonists (triptans) and dihydroergotamine are the most effective agents in this category. Significant vascular or cardiac disease, uncontrolled hypertension, and uncommon basilar migraine variants are contraindications to migraine-specific drugs.

**Treatment**

- Secondary headaches are managed through treatment of the underlying pathology.
- Tension-type headache:
  - Relaxation training and stress management.
  - Limit simple or combination analgesics to 2 or 3 days per week.
  - Trial of tricyclic or newer antidepressant for frequent occurrences.
  - Amitriptyline and stress management more effective than either therapy alone.
- Episodic cluster headache.
  - Oxygen delivered at 7 to 12 L/min for 25 min. is first line treatment.
  - Corticosteroids or ergotamine tartrate are short-term preventive agents.
  - Long cluster episodes may require verapamil, methysergide, or lithium carbonate.
  - Only highly effective abortive agent is subcutaneous sumatriptan.
  - Alternative abortive agents parenteral dihydroergotamine, intranasal sumatriptan, and intranasal lidocaine.
- Migraine headache
  - Treat acute attacks rapidly, effectively, and consistently.
  - NSAIDs (oral) and combination analgesics containing caffeine as first-line treatment that have been responsive in past.
  - Long cluster episodes may require verapamil or lithium carbonate.
  - If not symptom-free in 2 hours, try triptans or dihydroergotamine
  - Limit acute therapies to 2 days a week to avoid rebound headaches.
  - Treat acute migraines early, while it remains in the
Headache
Assessment and Management

There are several strategies for acute management of migraine. A model based on stratified care (treatment intensity matched to headache disability) has been demonstrated to be superior to models based on step care (milder first-line and stronger second-line agents). Experts recommend limiting acute therapies to two days per week to avoid headache from medication overuse.

The goals of acute therapy are to:
- Treat attacks rapidly, effectively, and consistently to reverse or prevent disability
- Minimize requirements for rescue medication
- Optimize self-care

A growing body of evidence supports the early treatment of acute migraine headache while it remains in the mild phase. This approach maximizes pain-free efficacy and minimizes adverse events and headache recurrence. Triptan treatment administered while the pain from migraine remains mild can also result in substantially reducing the total cost per treated attack. Since the majority of migraine sufferers do not have consistent complete relief with any individual treatment, a program combining two possible treatments may be preferred over those regimens providing a single option for acute attacks.

Preventive Therapy
Evidence supports recommendations for relaxation training, thermal or electromyogram biofeedback, and cognitive-behavioral therapy used alone or in combination with pharmacological therapies in both the stabilization and prevention of migraine. Some small studies support modest efficacy of magnesium, riboflavin, and feverfew. Other helpful nonpharmacological recommendations include:
- Regulation of sleep, meals, and exercise patterns
- Reduction of dietary and pharmacological stimulants
- Avoidance of triggers
- Preventive pharmacological agents.
  - Tricyclic antidepressants
  - Certain beta-blockers
  - Anticonvulsants
  - Benefits may take 2 months to manifest.
- Strong therapeutic partnership between physician and patient often lead to successful treatment

Pharmacological migraine-preventive agents are indicated in the following situations:
- Headache frequency more than twice per week
- Contraindication to, failure of, or adverse effects from acute therapies
- Presence of unusual migraine syndromes (hemiplegic, basilar, prolonged aura, migrainous infarction)
- Patient preference

The goals of preventive therapy include reduction of attack frequency, severity, and duration. Improved responsiveness to acute treatments may also occur. Recommended first-line agents for migraine headache prevention include certain beta-blockers, tricyclic antidepressants, and anticonvulsants. Clinical benefit may take two
months to manifest. After a six-month period of relative stability, tapering the patient off the drug should be considered. To ensure optimal effectiveness of preventive therapy overuse of acute medications (more than two days per week) should be avoided.

A strong therapeutic partnership between physician and patient, stressing patient education, often leads to successful outcomes in treatment of headaches.24 This should include the following aspects:

- Discussion of the risks, benefits, and realistic expectations of both acute and preventive medications is essential.
- Encouraging active participation through lifestyle suggestions and use of a headache calendar is useful.
- Diaries documenting headache events, triggers, and response to treatments are indispensable for monitoring progress on a regular basis.

<table>
<thead>
<tr>
<th>Acute Therapies</th>
<th>Preventive Therapies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use nonsteroidal anti-inflammatory drugs as first-line therapy:</td>
<td>Recommended first-line agents</td>
</tr>
<tr>
<td>Aspirin (325-975 mg/dose by mouth)*</td>
<td><strong>Amitriptyline</strong> (25-150 mg/d)***</td>
</tr>
<tr>
<td>Ibuprofen (400-800 mg/dose by mouth)*</td>
<td><strong>Divalproex sodium</strong> (500-1500 mg/d)*</td>
</tr>
<tr>
<td>Naproxen sodium (375-550 mg/dose by mouth)*</td>
<td><strong>Propranolol</strong> (80-240 mg/d)*</td>
</tr>
<tr>
<td>Tolprofen (200-400 mg/dose by mouth)†</td>
<td><strong>Timolol</strong> (20-30 mg/d) (<strong>not QUEST</strong></td>
</tr>
<tr>
<td>Combination of acetaminophen + aspirin + caffeine (2 tablets per dose by mouth)</td>
<td><strong>Sodium valproate</strong> (800-1500 mg/d)*</td>
</tr>
</tbody>
</table>


Bold = Preferred/Generic on SELECT  
*QUEST  
†Not available in the U.S.


The following recommendations are based on the U.S. Preventive Services Task Force, Centers for Disease Control and Prevention, the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, the American Academy of Family Practice, and the Hawaii State Department of Health.

Note: Primary preventive services screening recommendations are for asymptomatic, average-risk individuals.

Individuals at increased risk for any health conditions, you may need certain preventive services at a younger age or more often.

### Screening

<table>
<thead>
<tr>
<th>Screening</th>
<th>Age</th>
<th>Recommended frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Well-baby check (Growth/development assessment)</td>
<td>First year</td>
<td>Seven exams in the first year*</td>
</tr>
<tr>
<td></td>
<td>Second year</td>
<td>15, 18 and 24 months</td>
</tr>
<tr>
<td></td>
<td>3-5 years</td>
<td>Annually</td>
</tr>
<tr>
<td></td>
<td>6-18 years</td>
<td>Every 2-3 years with clinical judgment**</td>
</tr>
<tr>
<td>Eye exam</td>
<td>3-4 years</td>
<td>Regular visits to dental provider; brush/floss daily</td>
</tr>
<tr>
<td>Dental exam</td>
<td>Ongoing</td>
<td>Repeat as appropriate for populations at risk</td>
</tr>
<tr>
<td>TB Test</td>
<td>At 12 months, and before school entry</td>
<td></td>
</tr>
</tbody>
</table>

### Immunizations

See Recommended Childhood Immunization schedule (next page)

### Counseling Education

<table>
<thead>
<tr>
<th>Counseling Education</th>
<th>Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child safety car seat</td>
<td>5 years and younger</td>
</tr>
<tr>
<td>Lap shoulder car belt</td>
<td>5 years and older</td>
</tr>
<tr>
<td>Bike safety/injury protection</td>
<td>Ongoing</td>
</tr>
<tr>
<td>UV ray protection</td>
<td>Ongoing</td>
</tr>
<tr>
<td>High-risk sexual behavior</td>
<td>12 years or older</td>
</tr>
<tr>
<td>Unintended pregnancy</td>
<td></td>
</tr>
<tr>
<td>Tobacco, alcohol, drugs</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Diet, exercise</td>
<td></td>
</tr>
</tbody>
</table>

*The first exam is done in the hospital shortly after birth.

**The Hawaii State Department of Health recommends periodic exams for children in grades 1, 4, 7 and 10. (Some childhood immunizations required for school entry @ K and grade 7)
1. Hepatitis B (HepB) vaccine. All infants should receive the first dose of hepatitis B vaccine soon after birth and before hospital discharge; the first dose may also be given by age 2 months if the infant’s mother is hepatitis B surface antigen (HBsAg) negative. Only monovalent HepB can be used for the birth dose. Monovalent or combination vaccine containing HepB may be used to complete the series. Four doses of vaccine may be administered when a birth dose is given. The second dose should be given at least 4 weeks after the first dose, except for combination vaccines which cannot be administered before age 6 weeks. The third dose should be given at least 16 weeks after the first dose and at least 8 weeks after the second dose. The last dose in the vaccination series (third or fourth dose) should not be administered before age 24 weeks.

Infants born to HBsAg-positive mothers should receive HepB and 0.5 mL of Hepatitis B Immune Globulin (HBIG) within 12 hours of birth at separate sites. The second dose is recommended at age 1 to 2 months. The last dose in the immunization series should not be administered before age 24 weeks. Infants born to mothers whose HBsAg status is unknown should receive the first dose of the HepB series within 12 hours of birth. Maternal blood should be drawn as soon as possible to determine the mother’s HBsAg status; if the HBsAg test is positive, the infant should receive HBIG as soon as possible (no later than 1 week). The second dose is recommended at age 1 to 2 months. The last dose in the immunization series should not be administered before age 24 weeks.

2. Diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccine. The fourth dose of DTaP may be administered as early as age 12 months, provided 6 months have elapsed since the third dose and the child is unlikely to return at age 15 to 18 months. The final dose in the series should be given at age ≥4 years. Tetanus and diphtheria toxoids (Td) is recommended at age 11 to 12 years if at least 5 years have elapsed since the last dose of tetanus and diphtheria toxoid-containing vaccine. Subsequent routine Td boosters are recommended every 10 years.

3. Haemophilus influenzae type b (Hib) conjugate vaccine. Three Hib conjugate vaccines are licensed for infant use. If PRP-OMP (PedvaxHIB or ComVax [Merck]) is administered at ages 2 and 4 months, a dose at age 6 months is not required. DTaP/Hib combination products should not be used for primary immunization in infants at ages 2, 4 or 6 months but can be used as boosters following any Hib vaccine. The final dose in the series should be given at age ≥12 months.

4. Measles, mumps, and rubella vaccine (MMR). The second dose of MMR is recommended routinely at age 4 to 6 years but may be administered during any visit, provided at least 4 weeks have elapsed since the first dose and both doses are administered beginning at or after age 12 months. Those who have not previously received the second dose should complete the schedule by the 11- to 12-year-old visit.

5. Varicella vaccine. Varicella vaccine is recommended at any visit at or after age 12 months for susceptible children (i.e., those who lack a reliable history of chickenpox). Susceptible persons age ≥13 years should receive 2 doses, given at least 4 weeks apart.

6. Pneumococcal vaccine. The heptavalent pneumococcal conjugate vaccine (PCV) is recommended for all children age 2 to 23 months. The final dose in the series should be given at age ≥12 months. Pneumococcal polysaccharide vaccine (PPV) is recommended in addition to PCV for certain high-risk groups. See MMWR 2000;49(RR-9):1-38.

7. Hepatitis A vaccine. Hepatitis A vaccine is recommended for children and adolescents in selected states and regions and for certain high-risk groups; consult your local public health authority. Children and adolescents in these states, regions, and high-risk groups who have not been immunized against hepatitis A can begin the hepatitis A immunization series during any visit. The 2 doses in the series should be administered at least 6 months apart. See MMWR 1999;48(RR-12):1-37.

8. Influenza vaccine. Influenza vaccine is recommended annually for children age ≥6 months with certain risk factors (including but not limited to children with asthma, cardiac disease, sickle cell disease, human immunodeficiency virus infection, and diabetes; and household members of persons in high-risk groups). Established high-risk groups include children age 2 to 23 months who are household contacts of persons in high-risk categories. Additional children whose age 6 to 23 months are recommended to receive influenza vaccine if feasible, because children in this age group are at substantially increased risk of influenza-related hospitalizations. For healthy persons age 5 to 49 years, the trivalent inactivated vaccine (TIV) is recommended for children age ≥6 months with certain risk factors (including but not limited to children with asthma, cardiac disease, sickle cell disease, human immunodeficiency virus infection, and diabetes; and household members of persons in high-risk groups). Established high-risk groups include children age 2 to 23 months who are household contacts of persons in high-risk categories. Additional children whose age 6 to 23 months are recommended to receive influenza vaccine if feasible, because children in this age group are at substantially increased risk of influenza-related hospitalizations. For healthy persons age 5 to 49 years, the intranasal live-attenuated influenza vaccine (LAIV) is an acceptable alternative to the intramuscular trivalent inactivated influenza vaccine (TIV). See MMWR 2003;52(RR-13):1-8. Children receiving TIV should be administered a dosage appropriate for their age (0.25 mL if age 6 to 35 months or 0.5 mL if age ≥3 years). Children age ≥8 years who are receiving influenza vaccine for the first time should receive 2 doses (separated by at least 4 weeks for TIV and at least 6 weeks for LAIV).

For additional information about vaccines, including precautions and contraindications for immunization and vaccine shortages, please visit the National Immunization Program Web site at www.cdc.gov/nip/ or call the National Immunization Information Hotline at 800-232-2522 (English) or 800-232-0233 (Spanish).

Approved by the Advisory Committee on Immunization Practices (www.cdc.gov/nip/acip), the American Academy of Pediatrics (www.aap.org), and the American Academy of Family Physicians (www.aafp.org).
The following recommendations for men are based on the U.S. Preventive Services Task Force, the American Diabetes Association, and the Hawaii State Department of Health. Their appropriate use should be a shared decision between physician and patient.

Individuals at increased risk for any health conditions, you may need certain preventive services at a younger age or more often.

<table>
<thead>
<tr>
<th>SCREENING</th>
<th>AGE</th>
<th>RECOMMENDED FREQUENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood pressure</td>
<td>18 and older</td>
<td>At each office visit or every 2 years for normotensive adults</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>35-65 years</td>
<td>Every 5 years</td>
</tr>
<tr>
<td>FOBT and/or Sigmoidoscopy</td>
<td>50 years and older</td>
<td>Annually</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Every 5 years</td>
</tr>
<tr>
<td>Random or fasting plasma glucose test</td>
<td>45 years and older</td>
<td>Every 3 years</td>
</tr>
<tr>
<td>Eye exam</td>
<td></td>
<td>Clinical discretion</td>
</tr>
<tr>
<td>Hearing exam</td>
<td></td>
<td>Clinical discretion</td>
</tr>
<tr>
<td>Dental exam</td>
<td>Ongoing</td>
<td>Regular visits to dental provider; brush and floss daily</td>
</tr>
<tr>
<td>Depression</td>
<td>18 and older</td>
<td>Adults should be screened for depressions when accurate diagnosis, effective treatment, and follow-up care can be assured.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IMMUNIZATIONS</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Influenza vaccine</td>
<td>50 years and older</td>
<td>Annually</td>
</tr>
<tr>
<td>Pneumococcal vaccine</td>
<td>65 years or older</td>
<td>Younger if at increased risk due to chronic condition; revaccination for individuals vaccinated prior to age 65 if five or more years have elapsed</td>
</tr>
<tr>
<td>Td (tetanus, diphtheria) booster</td>
<td></td>
<td>Every ten years for adults; if five-dose series completed in childhood, every 15-30 years may be adequate</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>COUNSELING EDUCATION</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Tobacco, alcohol, drugs</td>
<td>Ongoing</td>
<td>Associated risks</td>
</tr>
<tr>
<td>Diet, exercise</td>
<td>Ongoing</td>
<td>Associated benefits</td>
</tr>
<tr>
<td>Lap shoulder car belt</td>
<td>Ongoing</td>
<td></td>
</tr>
<tr>
<td>Safety, injury prevention</td>
<td>Ongoing</td>
<td></td>
</tr>
<tr>
<td>High-risk sexual behavior</td>
<td>Ongoing</td>
<td></td>
</tr>
</tbody>
</table>
The following recommendations for women are based on the U.S. Preventive Services Task Force, the American Diabetes Association, and the Hawaii State Department of Health. Their appropriate use should be a shared decision between physician and patient.

Individuals at increased risk for any health conditions, you may need certain preventive services at a younger age or more often.

<table>
<thead>
<tr>
<th>Screening</th>
<th>Age</th>
<th>Recommended Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood pressure</td>
<td>18 and older</td>
<td>At each office visit or every 2 years for normotensive adults</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>45-65 years</td>
<td>Every 5 years</td>
</tr>
<tr>
<td>FOBT and/or Sigmoidoscopy</td>
<td>50 years and older</td>
<td>Annually</td>
</tr>
<tr>
<td>Pap smear</td>
<td>21-65 years (earlier if sexually active)</td>
<td>Every three years; within three years of onset of sexual activity</td>
</tr>
<tr>
<td>Chlamydia</td>
<td>25 years and younger</td>
<td>All sexually active women and other asymptomatic women at increased risk for infection</td>
</tr>
<tr>
<td>Mammography</td>
<td>40 years and older</td>
<td>Every 1-2 years. Women ages 40-49 years should seek clarification of the guidelines from their physicians as recommendation is for shared decision making in this age group</td>
</tr>
<tr>
<td>Random or fasting plasma glucose test</td>
<td>45 years and older</td>
<td>Every three years</td>
</tr>
<tr>
<td>Eye exam</td>
<td></td>
<td>Clinical discretion</td>
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<td>Dental exam</td>
<td>Ongoing</td>
<td>Regular visits to dental provider; brush and floss daily</td>
</tr>
<tr>
<td>Depression</td>
<td>18 and older</td>
<td>Adults should be screened for depression when accurate diagnosis, effective treatment, and follow-up care can be assured.</td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>High risk: 60 years and older</td>
<td>Normal risk: 65 years and older</td>
</tr>
</tbody>
</table>

*No studies have evaluated the optimal intervals for repeated screening. Because of limitations in the precision of testing, a minimum of 2 years may be needed to reliably measure a change in bone mineral density (BMD); however, longer intervals may be adequate for repeated screening to identify new cases of osteoporosis. Yield of repeated screening will be higher in older women, those with lower BMD at baseline, and those with other risk factors for fracture.

There are no data to determine the appropriate age to stop screening and few data on osteoporosis treatment in women older than 85. Patients who receive a diagnosis of osteoporosis fall outside the context of screening but may require additional testing for diagnostic purposes or to monitor response to treatment.
Primary Preventive Services

Women

(continued)

<table>
<thead>
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<tr>
<td>Td (tetanus, diphtheria) booster</td>
<td>Every ten years for adults; if five-dose series completed in childhood, every 15-30 years may be adequate</td>
<td></td>
</tr>
<tr>
<td>Rubella</td>
<td></td>
<td>Prior to childbearing age (if no documented history of immunization or disease)</td>
</tr>
</tbody>
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<td>Adequate calcium</td>
<td>Ongoing</td>
<td>Associated benefits</td>
</tr>
<tr>
<td>Lap shoulder car belt</td>
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<td>High-risk sexual behavior</td>
<td>Ongoing</td>
<td>Associated risks</td>
</tr>
<tr>
<td>Unintended pregnancy</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Introduction
Tobacco is the single greatest cause of disease and premature death in America today, and is responsible for more than 430,000 deaths each year. Nearly 25 percent of adult Americans currently smoke, and 3,000 children and adolescents become regular users of tobacco every day. The societal costs of tobacco-related death and disease approach $100 billion each year. However, more than 70 percent of all current smokers have expressed a desire to stop smoking; if they successfully quit, the result will be both immediate and long-term health improvements. Approximately 70 percent of smokers report seeing a physician each year, and cite a physician’s advice to quit as an important motivator. Because of their high credibility and frequent contact with smokers, clinicians can play a vital role in helping smokers quit.

Goals/Desired Outcomes
Efficacious treatments for tobacco users should become a part of standard caregiving by physicians.

Treatment
The following are guidelines that clinicians should use:
• Tobacco dependence is a chronic condition that often requires repeated intervention. However, effective treatments exist that can produce long-term or even permanent abstinence.
• Because effective tobacco dependence treatments are available, every patient who uses tobacco should be offered at least one of these treatments:
  o Patients willing to try to quit tobacco use should be provided treatments identified as effective in this guideline. (See Table A)
  o Patients not willing to try to quit tobacco use should be provided a brief intervention designed to increase their motivation to quit. (See Table B)
• It is essential that clinicians and health care delivery systems (including administrators, insurers, and purchasers) institutionalize the consistent identification, documentation, and treatment of every tobacco user who is seen in a health care setting.
• Brief tobacco dependence treatment is effective, and every patient who uses tobacco should be offered at least brief treatment.
• There is a strong dose-response relationship between the intensity of tobacco dependence counseling and its effectiveness. Treatments involving person-to-person contact (via individual, group, or proactive telephone counseling) are consistently effective, and their effectiveness increases with treatment intensity (e.g., minutes of contact).
Three types of counseling and behavioral therapies were found to be especially effective and should be used with all patients attempting tobacco cessation:

- Provision of practical counseling (problem solving/skills training);
- Provision of social support as part of treatment (intra-treatment social support); and
- Help in securing social support outside of treatment (extra-treatment social support).

Numerous effective pharmacotherapies for smoking cessation now exist. Except in the presence of contraindications, these should be considered with all patients attempting to quit smoking.

- Five first-line pharmacotherapies were identified that reliably increase long-term smoking abstinence rates:
  - Bupropion SR
  - Nicotine gum
  - Nicotine inhaler

- Two second-line pharmacotherapies were identified as efficacious and may be considered by clinicians if first-line pharmacotherapies are not effective:
  - Clonidine
  - Nortriptyline

- Over-the-counter nicotine patches are effective relative to placebo, and their use should be encouraged.

The panel encourages clinicians to use these recommendations to guide their treatment for smokeless tobacco, cigar and pipe users as well.

Other relevant findings include:

- Virtually all types of clinicians can effectively deliver tobacco cessation treatments.
- Very brief treatments, such as firm advice to quit smoking, can effectively boost long-term cessation.
Strategy 1
ASK — Systematically identify the tobacco-use status of every patient.
Implement an office-wide system to ensure that every patient be asked about his/her tobacco-use status, and that information is recorded in the medical record. Repeated assessment is not necessary in the case of an adult who has never smoked or has not smoked for many years, if this information is clearly documented in the medical record.

Strategy 2
ADVISE — Strongly urge all tobacco users to quit.
In a clear, strong, and personalized manner, urge every smoker to quit:
• Clear: “I think it is important for you to quit smoking now and I will help you. Cutting down while you are ill is not enough.”
• Strong: “As your doctor, I need you to know that quitting smoking is the most important thing you can do to protect your health.”
• Personalized: Link smoking to the patient’s current health/illness, the social and economic costs of tobacco use, motivation level, readiness to quit, and/or the impact of smoking on children and others in the household.

Encourage clinic staff to reinforce the cessation advice and support the patient’s attempt to quit.

Strategy 3
ASSESS — Determine willingness to make a quit attempt.
Ask every tobacco user if he or she is willing to make an attempt to quit at this time (e.g., within the next 30 days).

Strategy 4
ASSIST — Aid the patient in quitting.
Help the patient devise a plan to quit smoking. Set a quit date. Encourage treatment therapies except in special circumstances. Give key advice on successfully quitting: total abstinence, limiting or abstaining from drinking alcohol during the quitting process, and considering the potential influence of other smokers in the household.

Strategy 5
ARRANGE — Schedule follow-up contact.
Schedule follow-up contact, either in person or via telephone. Timing should occur soon after the planned quit date, preferably during the first week. Second follow-up contact is recommended within the first month. Congratulate success, review circumstances for smoking, elicit recommitment, assess treatments, and consider referral.
Patient Presents to a Health Care Setting (clinic, hospital, work site, others)

Does Patient Now Use Tobacco?

Is Patient Now Willing to Quit?

Did Patient Once Use Tobacco?

Provider Appropriate Tobacco Dependence Treatments

Promote Motivation Quit

Prevent Relapse*

No Intervention Required - Encourage Continued Abstinence

*Relapse prevention interventions are not necessary in the case of the adult who had not used tobacco for many years.