Provision of Training and Education for Participants

All student pharmacists participating in Operation Self-Care events should be provided with a copy of the material provided in this section of the planning guide. Participating pharmacists should also be provided with a copy of the material for reference purposes.

Approximately 1 to 2 weeks prior to the scheduled Operation Self-Care event, a live training session conducted by a faculty member should be held to review the basic principles applicable to the activity. Neither this module, nor the live training session, is intended to provide comprehensive heartburn education for student pharmacists. Only those guidelines and principles applicable to conducting screening programs are provided. It is recognized that students from each professional year may participate in screening events; therefore, the live training session is essential to ensure students at all levels are familiar with basic principles and procedures for the event. Participating pharmacists should also be invited to attend the live training session to become familiar with the procedures for the Operation Self-Care event.

Notice

Heartburn and dyspepsia are common symptoms that originate in the upper gastrointestinal (GI) tract. These symptoms are frequently treated with nonprescription medications. Heartburn (pyrosis) is a burning sensation that usually arises from the substernal area (lower chest) and moves up toward the neck or throat.1 Postprandial heartburn usually occurs within 2 hours after eating or when bending over or lying down. Nocturnal heartburn occurs during sleep and often awakens the individual. Most patients experience “simple” heartburn, which is typically mild, infrequent, episodic, and often associated with diet or lifestyle.1 Others have frequent heartburn (defined as heartburn that occurs 2 or more days a week). Heartburn that is frequent and persistent (3 or more months) is the most common typical symptom of gastroesophageal reflux disease (GERD). Patients with this chronic disease present with symptoms, esophageal damage, or both, which result from the abnormal reflux of gastric contents into the esophagus.2 About 20% to 30% of patients with GERD are diagnosed with endoscopic erosive esophagitis, whereas 60% to 70% suffer from heartburn, even when esophageal injury is not present at endoscopy (nonerosive gastroesophageal reflux disease; NERD).3 Although it is not life-threatening, patients with frequent heartburn limit their food choices and often suffer from disruptions in sleep and work.3 In 2000, the treatment of GERD ranked the highest in total direct and indirect costs (9.8 billion) among 17 selected GI diseases, with drug costs responsible for 63% of the direct costs.5

Dyspepsia (bad digestion) is a consistent or recurrent discomfort located primarily in the upper abdomen (epigastrium).1 The discomfort is a subjective feeling that does not reach the level of pain and is usually characterized by bloating, belching, postprandial fullness, nausea, and early satiety. The discomfort, however, is not necessarily restricted to meal-related symptoms. Patients with GERD, peptic ulcer disease (PUD), gastritis, delayed gastric emptying (e.g., gastroparesis), and irritable bowel syndrome (IBS) may complain of dyspeptic symptoms.3 Although the symptoms of IBS technically differ from those of dyspepsia, there is considerable overlap in the patient’s clinical description of these symptoms.

The Rome II consensus definition and regulatory agencies in the United States have adopted definitions of dyspepsia for research purposes that exclude heartburn, whereas other definitions consider heartburn an accompanying symptom of dyspepsia.4 Dyspepsia may be associated with an underlying cause such as PUD and GERD or may not have any known cause.5 Dyspepsia may be described as uninvestigated (no endoscopy has been performed) or investigated (endoscopy has been performed). Nonulcer dyspepsia is a diagnosis made at endoscopy, which indicates that “ulcerlike” dyspeptic symptoms are not related to a peptic ulcer. About 18 million adults in the United States take nonprescription medications for “indigestion.”1 The most widely used nonprescription medications include antacids, histamine-2-receptor antagonists (H2RAs), and proton pump inhibitors (PPIs).

In clinical practice, it is not always possible to predict the cause of heartburn or dyspepsia on the basis of symptom assessment alone, because individuals may not describe adequately what they actually feel. In addition, there is considerable overlap of symptoms. Heartburn and dyspepsia may also occur in association with other acid-related disorders, such as GERD and PUD, and may overlap with symptoms related to IBS. However, empirical treatment with nonprescription medications is appropriate and reasonable for most patients who have symptoms suggestive of heartburn and/or dyspepsia. Thus, assessment of the patient is most important in determining if the condition is self-treatable or if the individual should be referred for further evaluation. Medical referral is indicated if the patient is unresponsive to nonprescription medications, symptoms are severe, alarm symptoms are present, or symptoms suggest complicated disease.

This chapter focuses on the self-treatment and prevention of heartburn and dyspepsia. Emphasis is placed on distinguishing individuals who are appropriate candidates for self-treatment from those who require further medical evaluation. Specific recommendations for self-treatment, including dietary and lifestyle modifications and nonprescription medications, are provided.

The overall prevalence of heartburn in the United States is approximately 45% (about 110 million people), with an equal distribution between men and women of all age groups.1 Among individuals who experience heartburn, 45% report heartburn 2 or more days a week, whereas 7% to 10% report heartburn daily.9 Sixty-five percent of adults who experience heartburn at least once a week indicate that they have both daytime and nighttime heartburn.4 Most women who are pregnant experience heartburn during the course of their pregnancy.1

Approximately 25% of adults in the United States report having dyspeptic symptoms, with equal prevalence between men and women.7 A peptic ulcer is found in about 5% to 15% of patients with dyspepsia in North America, whereas esophagitis is identified in an additional 5% to 15% of cases at endoscopy.7 Gastric and esophageal cancer are less common causes but may also be associated with dyspeptic symptoms. Less than 50% of
Pathophysiology of Heartburn and Dyspepsia

The lower esophageal sphincter (LES) permits the passage of food into the stomach and serves as the primary antireflux barrier by preventing backflow of stomach contents upward into the esophagus (Figure 14-1). Although the LES is contracted at rest, healthy individuals experience relaxations of the LES throughout the day, often in association with swallowing.1 When reflux occurs, the refluxate is cleared from the esophagus through peristaltic contractions brought on by swallowing, through neutralization of the refluxate by bicarbonate in the swallowed saliva and, when in the upright position, through gravity. Esophageal mucosal resistance minimizes epithelial damage from noxious stomach contents. Thus, transient episodes of gastroesophageal reflux in healthy persons usually go unnoticed and do not damage the esophagus.

The stomach contains parietal cells that secrete hydrochloric acid and intrinsic factor (necessary for vitamin B₁₂ absorption), G cells that secrete gastrin, mucus-secreting cells, and chief cells that secrete pepsinogen.11,12 The parietal cells have receptors for histamine, acetylcholine, and gastrin, all of which stimulate hydrochloric acid secretion. When these substances come into contact with their receptors on the parietal cell, intracellular calcium and cyclic adenosine monophosphate (cAMP) concentrations increase.11 The increased levels of calcium and cAMP activate the proton pump, adenosine triphosphatase (H⁺/K⁺/ATPase), located in the membranes of the parietal cell. When stimulated, the proton pump secretes hydrogen ions into the stomach lumen in exchange for potassium. Thus, the proton pump is the final common pathway for gastric acid secretion. The gastric mucosa withstands the acidic environment of the stomach through a combination of defense and repair mechanisms that are collectively called the gastric mucosal barrier.12

Risk factors that contribute to heartburn include diet, lifestyle, medications, and certain diseases (Table 14-1).11,13-15 However, evidence to support each of the proposed risk factors is limited.14 Foods and beverages including coffee, tea, chocolate, and citrus; the regular use of aspirin and nonsteroidal anti-inflammatory drugs (NSAIDs); life stress; and tobacco smoking are widely recognized as precipitators of individual heartburn episodes.15 Heartburn may also occur during certain types of exercise (e.g., weight lifting, cycling, or sit-ups). Obesity and pregnancy contribute to reflux by a direct physical effect (e.g., disrupting the intra-abdominal pressure). Genetic factors may predispose to neurologic dysfunction of the LES.15 Diseases such as gastroparesis and scleroderma increase intra-abdominal pressure and lower LES pressure, respectively.

NSAIDs, including aspirin and cyclooxygenase-2 inhibitors, are very important causes of drug-induced dyspepsia.7 Bisphosphonates, potassium or iron supplements, digoxin, theophylline, and certain antibiotics (e.g., erythromycin, ampicillin) are often...
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Clinical Presentation of Heartburn and Dyspepsia

Heartburn may occur alone or be associated with acid-related disorders such as dyspepsia, GERD, and PUD (Table 14–2). Heartburn is highly specific for GERD and may suggest esophageal complications. However, the frequency and severity of heartburn are not predictive of esophageal injury, because many patients with frequent and severe heartburn may not have esophageal damage (e.g., NERD). Upper endoscopy is the standard for determining the type and extent of esophageal mucosal damage. Patients with esophageal injury may have varying grades of severity, including inflammation, erosions, and ulcers. This condition is more prevalent in men and increases with age. Barrett’s esophagus is associated with an increased risk of esophageal adenocarcinoma with an annual incidence of less than 1%.

Alarm symptoms can result from complications associated with GERD (Table 14–2). Dysphagia (difficulty in swallowing) occurs initially with the ingestion of solid foods such as toast or crackers and may be related to severe erosive esophagitis, esophageal stricture, or cancer. Odynophagia (painful swallowing) is less common but may also result from severe ulcerative esophagitis or esophageal cancer. However, the presence of odynophagia should raise questions about other causes of esophagitis including pill-induced (e.g., tetracycline, potassium chloride, quinine, vitamin C, aspirin, NSAIDs, or bisphosphonates) and infections (e.g., herpes or fungal candidiasis). Upper GI bleeding (e.g., hematemesis, melena, occult bleeding, or anemia) may also result from esophageal complications.

Abnormal gastric reflux of stomach contents may also cause atypical (extra-esophageal) manifestations of GERD (Table 14–2). The atypical symptoms may or may not be accompanied by heartburn, making recognition of GERD difficult. GERD-related chest pain is usually substernal, but it may mimic ischemic cardiac pain, radiating to the back, neck, jaw, or arms. It often worsens after meals and during periods of emotional stress, and may awaken the patient from sleep. Severe, crushing chest pain—especially if accompanied by nausea, vomiting, sweating, and shortness of breath—suggests ischemic pain and possibly myocardial infarction, and should be considered a medical emergency. However, the “typical” crushing chest pain usually associated with a myocardial infarction is more common in men than in women. Because women with ischemic cardiac pain may present differently than men, and because it is not possible clinically to differentiate cardiac pain from noncardiac pain, patients with these complaints should be referred to the emergency department. Other atypical symptoms result from the aspiration of refluxate into the upper airways and lungs.

Treatment of Heartburn and Dyspepsia

Treatment Goals

The goals of self-treatment of heartburn are to render the patient symptom-free, prevent meal- or exercise-related symptoms, improve quality of life, and prevent complications by using the most cost-effective therapy. The primary goal of self-treatment of dyspepsia is aimed at relieving abdominal discomfort.

General Treatment Approach

The approach to self-treatment of heartburn and dyspepsia requires an initial assessment to determine whether the patient...
is a candidate for self-treatment (Figure 14-2). Individuals with exclusions for self-treatment should be referred for further medical evaluation. If the individual is a candidate for self-treatment, nondrug measures should be recommended and continued throughout treatment (see the box Patient Education for Heartburn and Dyspepsia). If appropriate, a recommendation should also be made for a nonprescription medication. Antacids and nonprescription H2RAs should be recommended for individuals with mild, infrequent heartburn and dyspepsia. Antacids are advantageous because they provide rapid relief of symptoms (Table 14-3). The use of antacids, however, is limited by their short duration when taken on an empty stomach. The duration of relief may be prolonged for several hours by taking the antacid after a meal. When used in recommended dosages, the antacids are interchangeable despite differences in antacid salts and potency. Products that contain antacids plus alginic acid are also effective in relieving heartburn and may be superior to antacids alone. A combination of antacid and alginic acid is effective in treating heartburn and dyspepsia.

<table>
<thead>
<tr>
<th>TABLE 14-2</th>
<th>Differentiation of Simple Heartburn from Other Acid-Related Disorders</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Simple Heartburn</strong></td>
<td><strong>GERD</strong></td>
</tr>
<tr>
<td><strong>Etiology</strong></td>
<td>See Table 14-1</td>
</tr>
<tr>
<td><strong>Typical symptoms</strong></td>
<td>Burning sensation behind the breastbone that may move upward toward the neck or throat</td>
</tr>
<tr>
<td><strong>Complications</strong></td>
<td>Erosive esophagitis, strictures, bleeding, Barrett’s esophagus, esophageal cancer</td>
</tr>
<tr>
<td><strong>Alarm symptoms</strong></td>
<td>Dysphagia; odynophagia; chest pain; upper GI bleeding; unexplained weight loss; continuous nausea, vomiting, and diarrhea</td>
</tr>
<tr>
<td><strong>Atypical symptoms</strong></td>
<td>Asthma, chronic laryngitis, hoarseness, cough, globus sensation (sensation of a lump in the throat), noncardiac chest pain, dental erosions, sleep apnea</td>
</tr>
</tbody>
</table>

Key: GERD, gastroesophageal reflux disease; GI, gastrointestinal; NSAID, nonsteroidal anti-inflammatory drug; PUD, peptic ulcer disease.
interchangeable despite minor differences in potency, onset, and duration of action. Patients should not exceed 14 days of self-treatment with an H2RA without consulting their primary care provider.

Nonprescription PPIs are the drugs of choice for treatment of individuals with frequent heartburn occurring 2 or more days a week and for those who do not respond to nonprescription H2RAs. The onset of symptomatic relief following an oral dose of omeprazole is slower than that of an H2RA (Table 14-3), and complete relief of symptoms may take several days after initiating treatment. However, compared with the nonprescription H2RAs, the PPIs provide superior symptomatic relief and a prolonged duration of action. Patients should not take a nonprescription PPI for more than 14 days and should not re-treat more often than every 4 months unless under medical supervision.
nonprescription medications or consult their prescriber about

tion and nonprescription medications should be evaluated for

at least 3 hours before going to bed or lying down. Prescrip-

meals, to reduce intake of dietary fat, and to refrain from eating

sequently, heartburn sufferers should be counseled to eat smaller

Patient Education for Heartburn and Dyspepsia). Most impor-

tunate, contributing factors. Recommendations should be tailored to the

individual on the basis of specific dietary and lifestyle patterns.

Dietary and lifestyle modifications should be recommended for

all patients with heartburn and dyspepsia despite the fact that

evidence supporting their effectiveness is either lacking or

equivocal.2,14,15,21,22 These measures may benefit many individ-

uals, but such changes alone are unlikely to completely relieve

symptoms in the majority of patients.2,14,22 Nonpharmacologic

approaches to reducing the frequency and severity of heartburn

include actions to increase the LES pressure, decrease the intra-

gastric pressure, and assist in the movement of gastric contents.

A complete and accurate history will assist in identifying con-

tributing factors. Recommendations should be tailored to the

individual on the basis of specific dietary and lifestyle patterns.

Individuals should be asked to keep a diary to track dietary,

lifestyle, and medication “triggers” (Table 14–1). Weight loss

should be encouraged, although there is some controversy as to

whether this will significantly decrease symptoms.15,21 For noc-

turnal symptoms, relief may be attained from elevating the head

of the bed by placing 6-inch blocks underneath the legs of the

head of the bed, or placing a foam wedge (e.g., GERD pillow)

beneath the patient’s upper torso and head.14,21,23 Use of tradi-

tional pillows may worsen symptoms, because it causes the indi-

vidual to bend at the waist, which contributes to an increase in

intragastric pressure.

Because they are already dissolved or suspended, liquid

antacids may also increase LES pressure.1

Antacids act as buffering agents in the lower esophagus, gas-

tric lumen, and duodenal bulb. The cations react with chloride,

whereas the anionic portion of the molecule reacts with hydro-

gen ions to form water and other compounds. As a result, a small,

but noticeable, increase in intragastric pH occurs.24 Increasing the

intragastric pH above 5 blocks the conversion of pepsin to pep-

sinogen.24 Antacids may also increase LES pressure.1

Sodium bicarbonate rapidly reacts with gastric acid to form

sodium chloride, carbon dioxide, and water. Its duration of

action is shortened by its quick elimination from the stomach.24

Of the magnesium salts, magnesium hydroxide is used most

often. Magnesium hydroxide rapidly reacts with gastric acid to

form magnesium chloride and water. Its duration of action is

shorter than that of calcium carbonate and aluminum hydrox-

ide. Calcium carbonate is a potent antacid that dissolves slowly

in gastric acid to form calcium chloride, carbon dioxide, and

water. Its onset of action is slower, but its duration of effect is

longer than that of magnesium hydroxide or sodium bicarbon-

ate. Aluminum hydroxide reacts with hydrochloric acid to form

aluminum chloride and water. This agent has a slower onset but

a longer duration than those of magnesium hydroxide.

Because they are already dissolved or suspended, liquid

antacids usually have a faster onset than tablets and provide a

maximal surface area for action. Of the tablet dosage forms, the

quick-dissolve antacid tablets may provide the most rapid relief

of symptoms. The duration of action for all antacids is transient,

lasting only as long as the antacid remains in the stomach. The

presence of food affects the duration of action of antacids.

When administered within 1 hour after a meal, antacids may

remain in the stomach for up to 3 hours.24

Nonpharmacologic Therapy

Dietary and lifestyle modifications should be recommended for

The selection of a nonprescription medication for the self-

treatment of heartburn and dyspepsia should be based on the

frequency, duration, and severity of symptoms; the cost of the

medication; potential drug–drug interactions; and the patient’s

preference. Antacids, nonprescription H2RAs, and PPIs should

not be used beyond 2 weeks unless the individual is under med-

ical supervision. Individuals with severe, recurrent, or persistent

symptoms should be referred for medical evaluation.

TABLE 14–3 Effectiveness of Nonprescription Medications in Relieving Heartburn

<table>
<thead>
<tr>
<th>Medication</th>
<th>Onset of Relief</th>
<th>Duration of Relief</th>
<th>Symptomatic Relief</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antacids</td>
<td>&lt;5 minutes</td>
<td>20–30 minutes†</td>
<td>Excellent</td>
</tr>
<tr>
<td>H2RAs</td>
<td>30–45 minutes</td>
<td>4–10 hours</td>
<td>Excellent</td>
</tr>
<tr>
<td>H2RA + antacid</td>
<td>&lt;5 minutes</td>
<td>8–10 hours</td>
<td>Excellent</td>
</tr>
<tr>
<td>PPIs</td>
<td>2–3 hours</td>
<td>12–24 hours</td>
<td>Superior</td>
</tr>
</tbody>
</table>

Key: H2RA, histamine2-receptor antagonist; PPI, proton pump inhibitor.
† Food prolongs duration of relief.

Antacids relieve heartburn and dyspepsia by neutralizing gastric

acid. Nonprescription antacid products contain at least one of the

following salts: magnesium (hydroxide, carbonate, trisili-
cate); aluminum (hydroxide, phosphate); calcium carbonate;

and sodium bicarbonate (Table 14–4). Over the last few years,

many pharmaceutical manufacturers have reformulated antacid

products that had long-standing trade names (e.g., Mylanta) and

introduced new products (e.g., Mylanta Supreme) and dosage

forms (e.g., Mylanta Ultimate Strength Chewables) with simi-

lar trade names. Many of these modifications have led to the

addition of calcium to the formulation or replacement of another

antacid salt with calcium (e.g., Maalox Total Stomach Relief

Maximum Strength). Most antacids are relatively inexpensive,

making them desirable products for the temporary relief of mild

and infrequent heartburn and dyspepsia.

Pharmacologic Therapy

Antacids

Antacids act as buffering agents in the lower esophagus, gas-

tric lumen, and duodenal bulb. The cations react with chloride,

whereas the anionic portion of the molecule reacts with hydro-

gen ions to form water and other compounds. As a result, a small,

but noticeable, increase in intragastric pH occurs.24 Increasing the

intragastric pH above 5 blocks the conversion of pepsin to pep-

sinogen.24 Antacids may also increase LES pressure.1

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quick-dissolve antacid tablets may provide the most rapid relief

of symptoms. The duration of action for all antacids is transient,

lasting only as long as the antacid remains in the stomach. The

presence of food affects the duration of action of antacids.

When administered within 1 hour after a meal, antacids may

remain in the stomach for up to 3 hours.24
Differences in antacids are determined primarily by the cation, specific salt, and potency. Antacid potency is based on the number of milliequivalents of acid neutralizing capacity (ANC), which is defined as the amount of acid buffered per dose over a specified period of time. Factors that contribute to ANC include product formulation, ingredients, and concentration. As a result, ANC is product-specific, which means equal volumes of liquid antacids or the same number of tablets is not necessarily equal in potency.

Most antacids are minimally absorbed into the systemic circulation. About 90% of calcium is converted to insoluble calcium salts; the remaining 10% is absorbed systemically. Approximately 15% to 30% of magnesium and 17% to 30% of aluminum may be absorbed and then excreted renally; therefore, accumulation may occur in patients with renal insufficiency. In contrast, sodium bicarbonate is readily absorbed and eliminated.

Antacids are indicated for the treatment of mild, infrequent heartburn, sour stomach, and acid indigestion. Combination products containing aspirin or acetaminophen are indicated for overindulgence in food and drink, and hangover. Individuals with mild dyspepsia may experience some relief with antacids, but no studies demonstrate their effectiveness.

Antacids are administered orally. The effective dose of an antacid varies depending on product ingredients, milliequivalents of ANC, formulation, and the frequency and severity of symptoms. Individuals should be instructed to take product-specific recommended dosages at the onset of symptoms. Dosing may be repeated in 1 to 2 hours, if needed, but should not
exceed the maximum daily dosage for a particular product (Table 14–4). Individuals should be reevaluated if antacids are used more than twice a week or regularly for over 2 weeks. Frequent antacid users may need to be switched to a longer-acting product such as an H₃RA, an H₂RA plus an antacid, or a PPI.

Antacids are usually well tolerated. Side effects are generally associated with the cation. The most common side effect associated with magnesium-containing antacids is dose-related diarrhea. Diarrhea may be reduced by combining magnesium-containing antacids with aluminum hydroxide. However, when higher dosages are used, the predominating effect is diarrhea. Magnesium excretion is impaired in patients with renal disease and may result in systemic accumulation of magnesium. Magnesium-containing antacids should not be used in patients with a creatinine clearance of less than 30 mL/minute.

Aluminum-containing antacids are associated with dose-related constipation. Aluminum hydroxide binds dietary phosphate in the GI tract, increasing phosphate excretion in the feces. Frequent and prolonged use of aluminum hydroxide may lead to hypophosphatemia. Chronic use of aluminum-containing antacids in renal failure may lead to aluminum toxicity and should be avoided.

Calcium carbonate may cause belching and flatulence as a result of carbon dioxide production. Patients may complain of constipation when taking calcium antacids, but there is little evidence to support this side effect. Calcium stimulates gastric acid secretion and is hypothesized to cause acid rebound when calcium-containing antacids are used to treat acid-related disorders. The clinical importance of this finding, however, remains uncertain. If renal elimination is impaired, hypercalcemia may occur and accumulation of calcium may result in the formation of renal calculi. Because many antacids have been formulated to contain calcium, the risk of hypercalcemia exists when high and frequent dosages of calcium-containing antacids are taken with other calcium supplements or foods such as milk or orange juice with added calcium. Up to 2500 mg/day of elemental calcium can be ingested safely in individuals with normal renal function. (See Chapter 23 for discussion of calcium supplementation.)

Sodium bicarbonate frequently causes belching and flatulence resulting from the production of carbon dioxide. The high sodium content (274 mg sodium/gram sodium bicarbonate) may cause fluid overload in patients with congestive heart failure, renal failure, cirrhosis, pregnancy, and in those on sodium-restricted diets. In individuals with normal renal function, additional bicarbonate is excreted, whereas in patients with impaired renal function, retained bicarbonate may cause systemic alkalosis. A high intake of calcium along with an alkalinizing agent (such as sodium bicarbonate or calcium carbonate) may produce a condition referred to as milk–alkali syndrome. Signs and symptoms include hypercalcemia, alkalosis, irritability, headache, nausea, vomiting, weakness, and malaise. Individuals who take calcium supplements should avoid using sodium bicarbonate as an antacid.

All antacids may potentially increase or decrease the absorption of other oral medications when given concomitantly, by adsorbing or chelating the other drug or increasing intragastric pH. Medications such as tetracyclines, azithromycin, and fluoroquinolones bind to divalent and trivalent cations, potentially decreasing antibiotic absorption. The absorption of medications such as itraconazole, ketoconazole, and iron, which depend on a low intragastric pH for disintegration, dissolution, or ionization, may also be decreased. Specific antacids, such as aluminum hydroxide, may decrease the absorption of isoniazid. The absorption of enteric-coated products may be increased with concurrent administration of antacids. The intraluminal interactions of antacids with other oral medications can usually be avoided when potentially interacting drugs are separated by at least 2 hours. Antacid-induced alkalinization of the urine may increase urinary excretion of salicylates and decrease blood concentrations.

In contrast, an increase in urine pH may decrease urinary excretion and increase blood concentrations of amphetamines and quinidine.

Alginate react with sodium bicarbonate in saliva to form a viscous layer of sodium alginate that floats on the surface of gastric contents, theoretically forming a protective barrier against esophageal irritation. Alginate by itself does not neutralize acid. Because there is insufficient evidence supporting its efficacy as a single agent, the Food and Drug Administration (FDA) has not granted alginate acid category I status. However, alginate acid may be found as an inactive ingredient in several antacid products (Table 14–4). Combination products of alginate acid and an antacid may be superior to an antacid alone. Several antacid products contain simethicone to decrease discomfort related to intestinal gas. (See Chapter 15 for a more detailed description of simethicone.)

**Histamine₂-Receptor Antagonists**

Cimetidine, ranitidine, famotidine, and nizatidine are available for nonprescription use (Table 14–5) in one-half of the prescription dose and in the higher prescription dose. These H₂RAs are considered interchangeable, despite differences in onset and duration of symptomatic relief, side effects, and the potential for drug–drug interactions. The H₂RAs decrease fasting and food-stimulated gastric acid secretion and gastric volume by inhibiting histamine on the histamine, receptor of the parietal cell. Therefore, the H₂RAs are effective in relieving fasting and nocturnal symptoms. Their bioavailability is not affected by food but may be reduced modestly by antacids. Onset of symptomatic relief is not as rapid as with antacids, but the duration of effect is longer (Table 14–3). Cimetidine is the shortest-acting (4–8 hours), whereas ranitidine, famotidine, and nizatidine have a somewhat longer duration. Tolerance to the gastric antisecretory effect may develop when H₂RAs are taken daily (versus as needed) and may be responsible for diminished efficacy. Therefore, it is preferable to take an H₂RA on an as-needed basis rather than continuously every day. All four H₂RAs are eliminated by a combination of renal and hepatic metabolism, with renal elimination being the most important. Consideration should be given to reducing the daily H₂RA dose in patients with renal failure and patients of advanced age.

Nonprescription H₂RAs are indicated for the treatment of mild-to-moderate, infrequent, episodic heartburn and for the prevention of heartburn associated with acid indigestion and sour stomach. H₂RAs are more effective than placebo for relief of mild-to-moderate heartburn and provide moderate improvement in patients with mild dyspeptic symptoms. The combined antacid (magnesium hydroxide and calcium carbonate) and H₂RA (famotidine) product is indicated for individuals with postprandial heartburn who have not premedicated with an H₂RA. H₂RAs may be used at the onset of symptoms or 30 minutes to 1 hour prior to an event (meal or exercise) in which heartburn is anticipated. Self-treatment dosing should be limited to no more than two times a day. If the H₂RA is used for more than 2 weeks, a medical referral is recommended. The combined
antacid and H₂RA product provides immediate relief and a longer duration of effect.

H₂RAs are well tolerated and have a low incidence of side effects. The most common side effects reported with all four H₂RAs include headache, diarrhea, constipation, dizziness, and drowsiness. Cimetidine is associated with a weak antianastomotic effect that, when taken in high dosages, may result in decreased libido, impotence, or gynecomastia in men.

Cimetidine binds to hepatic cytochrome P450 (3A4, 2D6, and 2C9), inhibiting the metabolism of numerous drugs including phenytoin, warfarin, theophylline, tricyclic antidepressants, and amiodarone. Ranitidine binds to the cytochrome P450 system to a lesser extent, so interactions are uncommon at nonprescription doses. Famotidine and nizatidine do not interact with the cytochrome P450 system. Medications such as ketonazole,itraconazole,indinavir and atazanavir, and iron salts are dependent on an acidic environment for absorption. When administered with an acid-reducing product, their absorption may be reduced. Cimetidine may inhibit the renal tubular secretion of drugs such as procarbazine.

Proton Pump Inhibitors

PPIs are potent antacid drugs that relieve heartburn and dyspepsia by decreasing gastric acid secretion. Omeprazole magnesium 20.6 mg (Prilosec OTC) was the first PPI to become available for nonprescription use in the United States. It is converted in the body to omeprazole 20 mg. Nonprescription omeprazole 20 mg is also available as specific pharmacy-branded nonprescription products. Other PPIs are currently under consideration for a prescription-to-nonprescription switch and may soon be available. The PPIs inhibit hydrogen potassium ATPase (the proton pump), irreversibly blocking the final step in gastric acid secretion; therefore, they have a more potent and prolonged antisecretory effect than that of the H₂RAs (Table 14–3). The relative bioavailability of the prescription dosage form (enteric-coated granules contained in a capsule) increases from 35% to 65% with continued daily dosing. Nonprescription omeprazole is formulated as a tablet containing multiple enteric-coated pellets and has a similar oral bioavailability. Omeprazole is almost completely absorbed after oral administration, regardless of the presence of food. The tablet should not be chewed or crushed, because the effectiveness of the drug may be decreased.

Onset of symptomatic relief following an oral dose occurs in 2 to 3 hours, but complete relief may take 1 to 4 days. A recent study indicates that on day 1, the percentage of time the intragastric pH was greater than 4 with Prilosec OTC taken once daily was higher than with Pepcid AC taken twice a day and was comparable to famotidine 20 mg twice daily. In addition, the intragastric pH with Prilosec OTC was consistently higher than that of both famotidine regimens on subsequent treatment days.

Nonprescription PPIs are indicated for the treatment of frequent heartburn in patients who have symptoms 2 or more days a week. It is not intended for immediate relief of dyspepsia, or occasional or acute episodes of heartburn. Because PPIs inhibit only those proton pumps that are actively secreting acid, they are most effective when taken 30 minutes before a meal. Nonprescription PPIs should be taken every morning for 14 days. Treatment of heartburn may be repeated after 4 months if symptoms recur. If heartburn continues while taking a nonprescription PPI, persists for more than 2 weeks, or recurs within 4 months, further medical evaluation is recommended.

The most common short-term side effects of PPIs are similar to those reported for the H₂RAs (i.e., diarrhea, constipation, and headache). Recent retrospective case-controlled studies of large databases have shown an association between PPIs and community-acquired pneumonia, Clostridium difficile infection, and an increased risk for hip fractures in individuals older than 50 years. Possible increased risk of pneumonia may result from a decrease in the antibacterial action of gastric juice, which when aspirated may lead to an overgrowth of pathogens. Risk factors include asthma, chronic obstructive pulmonary disease, young or old age (e.g., children and elderly), and immunocompromised state. Although an increased risk of bacterial gastroenteritis and C. difficile infection has been reported, another population-based...
Bismuth Subsalicylate

Bismuth subsalicylate (BSS) is indicated for heartburn, upset stomach, indigestion, nausea, and diarrhea. FDA has tentatively determined that BSS is safe and effective for the relief of upset stomach associated with belching and gas associated with overindulgence in food and drink. It is uncertain how BSS relieves heartburn, but for upset stomach, it is believed to act by a topical effect on the stomach mucosa. When used to treat acid-related symptoms, the adult dose of BSS is 262 to 525 mg every one-half to 1 hour as needed (Table 14-4). Recently, numerous nonprescription products have been reformulated to contain BSS. In the past, common trade-name products, such as Maalox, contained only antacids. Today, product line extensions, such as Maalox Total Stomach Relief, contain BSS and no antacid (Table 14-4). Therefore, health care providers and patients are often confused and may not know what they are recommending or purchasing, respectively. Individuals taking these products need to know that bismuth salts may cause the stool and tongue to turn black. Dark-colored stools may be interpreted as a more severe underlying disorder. If self-treatment is appropriate, an assessment should be made to determine if the individual has renal impairment and to identify potentially interacting medications. Patients with decreased renal function should be cautioned about using aluminum- and magnesium-containing antacids. The daily H,RA dose should also be reduced, especially in those taking the higher nonprescription dosages. Omeprazole may be used in patients with renal impairment. Sodium bicarbonate should be avoided in patients taking cardiovascular medications.

Antacid selection for eligible patients should be based, in part, on potential side effects. For example, if a patient has a tendency toward constipation, a less constipating antacid, such as magnesium hydroxide, may be more appropriate, whereas constipating antacids, such as aluminum hydroxide, should be avoided.

Children under 12 years of age with heartburn or dyspepsia should be referred to their primary care provider for further evaluation. Non-prescription antacids such as calcium carbonate and magnesium hydroxide are labeled for children 12 years and older. If antacids are recommended, an assessment of the child's average daily intake of calcium may help guide the recommendation. The recommended daily intake of calcium for children 9 to 18 years old is 1300 mg. Non-prescription H,RA are labeled for patients 12 years and older, and non-prescription omeprazole is indicated for patients 18 years and older.

Infrequent and mild heartburn in pregnant women should be treated initially with dietary and lifestyle modifications. Calcium- and magnesium-containing antacids are Pregnancy Category B agents; they may be used safely if the recommended daily dosages are not exceeded. Special attention should be given to the recommended intake of calcium during pregnancy (1000–1300 mg/day). If a woman is meeting the recommendations, the addition of a calcium-containing antacid may cause her to exceed the upper limit of 2500 mg of calcium per day. Pregnant women with frequent and moderate-to-severe heartburn should be referred for medical evaluation. Although cimetidine, ranitidine, and nizatidine are listed as Pregnancy Category B and have been used during pregnancy, women should seek medical advice prior to self-treating with an H,RA. Omeprazole is a Pregnancy Category C drug and should not be used by pregnant women without medical supervision.

Magnesium hydroxide and aluminum hydroxide are not secreted into breast milk in substantial amounts. Therefore, these antacids may be safely recommended for self-treatment of heartburn in nursing mothers. The American Academy of Pediatrics considers cimetidine to be compatible with breast-feeding. However, ranitidine and famotidine are less concentrated in the breast milk and may be preferable. There is insufficient information regarding the use of omeprazole in women who are breast-feeding, so it cannot be recommended for nursing mothers at this time.

PATIENT PREFERENCES

Antacids and antisecretory drugs are available in a wide range of prices, flavors, and dosage forms. Once the most appropriate non-prescription medication is determined, the individual should be involved in selecting a product that is affordable, palatable, and practical to administer. Other nonactive ingredients such as dyes, sodium, and sugar should be considered for individuals with allergies, sensitivities, or dietary restrictions.

Complementary and Alternative Therapies

There is no evidence that botanical natural products increase intragastric pH and relieve heartburn. A few studies have shown an improvement in dyspeptic symptoms with a combination of herbs. Limited studies of products containing various combinations of ibers, peppermint, chamomile, bitter candy tuft, matrica flower, caraway, licorice root, and lemon balm demonstrated
Heartburn and Dyspepsia

CHAPTER 14

Assessment of Heartburn and Dyspepsia: A Case-Based Approach

Cases 14-1 and 14-2 illustrate the assessment of patients with heartburn and dyspepsia.

Patient Counseling for Heartburn and Dyspepsia

Many cases of uncomplicated heartburn and dyspepsia are self-treatable. For optimal outcomes, individuals need to understand how to treat symptoms appropriately and when to seek additional care. This information is provided in the box Patient Education for Heartburn and Dyspepsia.

Evaluation of Patient Outcomes for Heartburn and Dyspepsia

Individuals taking antacids or an H₂RA for infrequent heartburn and dyspepsia should obtain symptomatic relief within 30 minutes to 1 hour. Patients taking omeprazole may require up to 4 days for complete relief of symptoms, but most individuals are asymptomatic within 1 or 2 days. Self-treating individuals should be encouraged to contact their health care provider to report on the effectiveness of therapy and problems, such as side effects, that may arise during treatment. In some cases, the clinician may provide a follow-up phone call to assess therapeutic outcomes. Patients should be asked to describe the change in frequency and severity of symptoms since they initiated therapy. They should be questioned regarding side effects and any new symptoms that may have developed. If an inadequate response is noted, the individual should be reevaluated to determine if a different product is suitable or if medical referral is necessary. Side effects may be managed by adjusting dosage or switching to another product. Development of atypical or alarm symptoms (Table 14-2) should be referred to a primary care provider.

### Relevant Evaluation Criteria Scenario/Model Outcome

<table>
<thead>
<tr>
<th>Information Gathering</th>
<th>Scenario/Model Outcome</th>
</tr>
</thead>
</table>
| **Patient complaints of recurring substernal burning sensation after eating heavy meals. It occurs once a week. The discomfort is rated a 4 on a scale of 1–10. It is associated with a feeling of fullness and occasional acid regurgitation. Symptoms typically last 2–4 hours after eating.** | **Jane Young** 36-year-old female, 5 ft 5 in, 165 lb  
Office manager  
Normal balanced diet; drinks 4–5 cups of coffee each day; drinks 3–4 alcoholic drinks when she goes out for dinner  
6–8 hours uninterrupted sleep each night  
Ethinyl estradiol/norgestimate contraceptive, venlafaxine 75 mg for depression, multivitamin every day, calcium citrate 630 mg with vitamin D 400 IU twice daily |
| **Symptoms occur after eating at restaurants or at potluck events at work.** | **Patient has tried drinking chamomile tea to help relieve the symptoms but has not noticed an improvement.** |

NKA

None
### Case 14-1 (continued)

<table>
<thead>
<tr>
<th>Relevant Evaluation Criteria</th>
<th>Scenario/Model Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assessment and Triage</strong></td>
<td>Infrequent postprandial substernal burning is consistent with uncomplicated heartburn.</td>
</tr>
<tr>
<td>3. Differentiate the patient’s signs/symptoms and correctly identify the patient’s primary problem(s) (see Table 14-2).</td>
<td>None</td>
</tr>
<tr>
<td>4. Identify exclusions for self-treatment (see Figure 14-2).</td>
<td>Options include: (1) Refer Jane to her primary care provider. (2) Recommend lifestyle modifications. (3) Recommend an OTC antacid or acid-suppressing product. (4) Take no action.</td>
</tr>
<tr>
<td>5. Formulate a comprehensive list of therapeutic alternatives for the primary problem to determine if triage to a medical practitioner is required, and share this information with the patient.</td>
<td>An OTC acid-suppressing product should be effective. Patient will consider lifestyle modifications.</td>
</tr>
<tr>
<td><strong>Plan</strong></td>
<td>Take famotidine 20 mg 30–60 minutes prior to a type of meal that precipitates symptoms (restaurant or potluck). See directions in Table 14-5.</td>
</tr>
<tr>
<td>6. Select an optimal therapeutic alternative to address the patient’s problem, taking into account patient preferences.</td>
<td>Seeking a PCP may not be necessary if symptoms remain mild and infrequent. An antacid will not provide long-lasting relief, and symptoms are not frequent enough to meet the criteria for a PPI at this time. Follow the administration guidelines in Table 14-5.</td>
</tr>
<tr>
<td>7. Describe the recommended therapeutic approach to the patient.</td>
<td>See Table 14-5.</td>
</tr>
<tr>
<td>8. Explain to the patient the rationale for selecting the recommended therapeutic approach from the considered therapeutic alternatives.</td>
<td>See the box Patient Education for Heartburn and Dyspepsia.</td>
</tr>
<tr>
<td><strong>Patient Education</strong></td>
<td>Can I take an antacid for immediate relief of symptoms?</td>
</tr>
<tr>
<td>9. When recommending self-care with nonprescription medications and/or nondrug therapy, convey accurate information to the patient:</td>
<td>Yes, taking a product that contains magnesium hydroxide after symptoms occur will provide faster relief. Avoid calcium-containing products, because you currently take calcium supplements.</td>
</tr>
<tr>
<td>a. Appropriate dose and frequency of administration</td>
<td>See Table 14-5.</td>
</tr>
<tr>
<td>b. Maximum number of days the therapy should be employed</td>
<td>See the box Patient Education for Heartburn and Dyspepsia.</td>
</tr>
<tr>
<td>c. Product administration procedures</td>
<td>See Table 14-5.</td>
</tr>
<tr>
<td>d. Expected time to onset of relief</td>
<td>See Table 14-3.</td>
</tr>
<tr>
<td>e. Degree of relief that can be reasonably expected</td>
<td>Complete prevention of symptoms if taken before meals; relief if taken at onset of symptoms</td>
</tr>
<tr>
<td>f. Most common side effects</td>
<td>Side effects are uncommon. Some patients report headache, diarrhea, or constipation.</td>
</tr>
<tr>
<td>g. Side effects that warrant medical intervention should they occur</td>
<td>None</td>
</tr>
<tr>
<td>h. Patient options in the event that condition worsens or persists</td>
<td>A PCP should be consulted if symptoms occur despite appropriate use of an H2RA, or if alarm symptoms occur. See Table 14-2.</td>
</tr>
<tr>
<td>i. Product storage requirements</td>
<td>See the box Patient Education for Heartburn and Dyspepsia.</td>
</tr>
<tr>
<td>j. Specific nondrug measures</td>
<td>Eat smaller meals. Reduce caffeine and alcohol consumption. See the box Patient Education for Heartburn and Dyspepsia for other measures.</td>
</tr>
<tr>
<td>10. Solicit follow-up questions from patient.</td>
<td></td>
</tr>
<tr>
<td>11. Answer patient’s questions.</td>
<td></td>
</tr>
</tbody>
</table>

Key: NKA, no known allergies; OTC, over-the-counter; PCP, primary care provider.
### Relevant Evaluation Criteria

<table>
<thead>
<tr>
<th>Information Gathering</th>
<th>Scenario/Model Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Gather essential information about the patient’s symptoms, including:</td>
<td>Patient suffers from recurrent upper abdominal discomfort. Pain is described as a gnawing or burning sensation, fluctuating throughout the day. Pain rating varies from 2–6 on a scale of 10. Symptoms started 2 months ago; they affect his appetite, resulting in a 10-lb weight loss.</td>
</tr>
<tr>
<td>a. description of symptom(s) (i.e., nature, onset, duration, severity, associated symptoms)</td>
<td>Symptoms seem to be relieved temporarily with food.</td>
</tr>
<tr>
<td>b. description of any factors that seem to precipitate, exacerbate, and/or relieve the patient’s symptom(s)</td>
<td>Patient has tried eating smaller meals, and has tried herbal teas and ranitidine 150 mg as needed. Improvement was not noticeable.</td>
</tr>
<tr>
<td>c. description of the patient’s efforts to relieve the symptoms</td>
<td></td>
</tr>
<tr>
<td>2. Gather essential patient history information:</td>
<td></td>
</tr>
<tr>
<td>a. patient’s identity</td>
<td>Yen Xu Wang</td>
</tr>
<tr>
<td>b. patient’s age, sex, height, and weight</td>
<td>64-year-old male, 5 ft 8 in, 185 lb</td>
</tr>
<tr>
<td>c. patient’s occupation</td>
<td>Grocery clerk</td>
</tr>
<tr>
<td>d. patient’s dietary habits</td>
<td>Traditional Chinese food</td>
</tr>
<tr>
<td>e. patient’s sleep habits</td>
<td>Averages 4 hours per night</td>
</tr>
<tr>
<td>f. concurrent medical conditions, prescription and nonprescription medications, and dietary supplements</td>
<td>Indomethacin 75 mg as needed and allopurinol 300 mg every day for gout, atenolol 50 mg every day, HCTZ 25 mg every day, verapamil ER 120 mg every day for hypertension, ginseng supplements every day</td>
</tr>
<tr>
<td>g. allergies</td>
<td>Codeine</td>
</tr>
<tr>
<td>h. history of other adverse reactions to medications</td>
<td>None</td>
</tr>
</tbody>
</table>

### Assessment and Triage

3. Differentiate the patient’s signs/symptoms and correctly identify the patient’s primary problem(s) (see Table 14-2).

4. Identify exclusions for self-treatment (see Figure 14-2 and Table 14-2).

5. Formulate a comprehensive list of therapeutic alternatives for the primary problem to determine if triage to a medical practitioner is required, and share this information with the patient.

### Plan

6. Select an optimal therapeutic alternative to address the patient’s problem, taking into account patient preferences.

7. Describe the recommended therapeutic approach to the patient.

8. Explain to the patient the rationale for selecting the recommended therapeutic approach from the considered therapeutic alternatives.

### Patient Education

9. When recommending self-care with nonprescription medications and/or nondrug therapy, convey accurate information to the patient.
Heartburn and dyspepsia (indigestion) are often self-treatable conditions. Heartburn is characterized by a burning sensation in the chest, usually occurring after meals. Dyspepsia is characterized by discomfort in the upper abdomen. The objectives of self-treatment are to (1) provide complete relief of symptoms, (2) reduce frequency of intermittent episodes, (3) manage factors that contribute to the development of symptoms, (4) prevent and manage side effects of selected treatment, and (5) improve quality of life.

Nondrug Measures
- Avoid food, beverages, and activities associated with an increased frequency and severity of symptoms.
- If possible, avoid the use of medications that may aggravate heartburn or dyspeptic symptoms.
- Avoid eating large meals.
- Stop or reduce smoking.
- Lose weight if overweight and not pregnant.
- Wear loose-fitting clothing.
- If nocturnal symptoms are present:
  - Avoid lying down within 3 hours of a meal.
  - Elevate the head of the bed using 6-inch blocks, or use a foam pillow wedge.

Nonprescription Medications
- Store all medications at 68°F to 77°F (20°C–25°C), and protect them from heat, humidity, and moisture. Discard after expiration date.

Antacids
- Antacids (sodium bicarbonate, calcium carbonate, magnesium hydroxide, and aluminum hydroxide) are available alone and in combination with each other and other ingredients.
- Antacids work by neutralizing acid in the stomach.
- Antacids may be used for relief of mild, infrequent heartburn or dyspepsia (indigestion).
- Antacids are usually taken at the onset of symptoms. Relief of symptoms begins within 5 minutes.
- Because antacids come in a variety of strengths and concentrations, it is essential to consult the label of an individual product for correct dosing quantities and frequencies. Generally antacids should not be used more than four times a day, or regularly for more than 2 weeks.
- If symptoms are not relieved with recommended dosages, consult a health care provider.
- Diarrhea may occur with magnesium- or magnesium/aluminum-containing antacids; constipation may occur with aluminum- or calcium-containing antacids. Consult with a health care provider if these effects are severe or do not resolve in a few days.
- Patients with renal impairment should consult with their primary care provider prior to self-treatment with antacids.
- Patients taking tetracyclines, fluoroquinolones, azithromycin, digoxin, ketoconazole, itraconazole, and iron supplements should not take antacids within 2 hours of taking any of these medications.

Histamine2-Receptor Antagonists
- H2RAs (cimetidine, famotidine, nizatidine, and ranitidine) may be used to prevent heartburn and indigestion associated with meals.
- H2RAs are usually taken at the onset of symptoms or 1 hour before symptoms are expected. Relief of symptoms can be expected to begin within 30–45 minutes. A combination product that contains both an antacid and an H2RA provides more rapid relief of symptoms.
- H2RAs generally relieve symptoms for 4–10 hours. H2RAs can be taken when needed up to twice daily for 2 weeks.
- H2RAs work by decreasing acid production in the stomach.
- H2RAs should be used for relief of mild-to-moderate, infrequent, and episodic heartburn and indigestion when a longer effect is needed; use lower dosages for mild infrequent heartburn and higher dosages for moderate infrequent symptoms.
- If symptoms are not relieved with recommended doses or persist after 2 weeks of treatment, consult a primary care provider.
- Side effects are uncommon. Consult a primary care provider if side effects are severe or do not resolve within a few days.
- Cimetidine may interact with certain prescription medications. Consult your primary care provider if you are taking a blood thinner such as warfarin, an antifungal such as ketoconazole, antidepressants, anticonvulsants, theophylline, or amiodarone.

Proton Pump Inhibitors
- Proton pump inhibitors (omeprazole) work by decreasing acid production in the stomach.
- Omeprazole is indicated for mild-to-moderate frequent heartburn that occurs 2 or more days a week. It is not intended for the relief of mild, occasional heartburn.
- Omeprazole should be taken with a glass of water every morning 30 minutes before breakfast for 14 days. Make sure that you take the full 14-day course of treatment.

<table>
<thead>
<tr>
<th>Relevant Evaluation Criteria</th>
<th>Scenario/Model Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>10. Solicit follow-up questions from patient.</td>
<td>Is there an herbal medication that would relieve the symptoms?</td>
</tr>
<tr>
<td>11. Answer patient’s questions.</td>
<td>There is insufficient evidence for effective herbal treatments for this condition. Your current symptoms indicate a need for prompt medical attention.</td>
</tr>
</tbody>
</table>

Key: N/A, not applicable; NKA, no known allergies; OTC, over-the-counter; PCP, primary care provider.
REFERENCES

➤ H2RAs are indicated for mild, infrequent heartburn or
➤ Antacids provide temporary relief for mild and infrequent heartburn and dyspepsia. Dosages are product-specific because of variability in antacid ingredients and concentrations.
➤ H2RAs are indicated for mild, infrequent heartburn or dyspepsia. They may be taken at the onset of symptoms or 1 hour prior to an event (meal or exercise) that causes symptoms.
➤ Combining an antacid with an H2RA provides immediate relief of heartburn and a longer duration of action.
➤ The nonprescription PPI omeprazole is indicated for the treatment of frequent heartburn (heartburn that occurs 2 or more days a week) and is not intended for immediate relief of infrequent symptoms.
➤ Advise individuals with self-treatable symptoms that if symptoms worsen or do not improve after 14 days of effective self-treatment, they should contact their primary care provider.

Patient Education for Heartburn and Dyspepsia (continued)

➤ Do not take more than 1 tablet a day.
➤ Complete resolution of symptoms should be noted within 4 days of initiating treatment.
➤ If symptoms persist, are not adequately relieved after 2 weeks of treatment, or recur before 4 months has elapsed since treatment, consult your primary care provider.
➤ Do not crush or chew tablet, or crush tablet in food or beverage; this may decrease omeprazole’s effectiveness.
➤ Side effects are uncommon. Consult with a health care provider if side effects are severe or do not resolve with a few days.
➤ Ask a health care provider if you are also taking blood thinners such as warfarin, antifungals such as ketoconazole, or anti-anxiety medications such as diazepam or digoxin.

Heartburn or dyspepsia after 2 weeks of continuous treatment with a non-prescription medication
Heartburn that awakens you during the night
Difficulty or pain on swallowing foods
Light-headedness, sweating, dizziness accompanied by vomiting blood or black material or black tarry bowel movements
Chest pain or shoulder, arm, neck pain, with shortness of breath
Chronic hoarseness, cough, choking, or wheezing
Unexplained weight loss
Continuous nausea, vomiting, or diarrhea
Severe stomach pain

Consult your primary care provider if you experience:

— Heartburn or dyspepsia for more than 3 months
— Heartburn or dyspepsia while taking recommended dosages of nonprescription medications

KEY POINTS FOR HEARTBURN AND DYSPEPSIA

➤ Limit the self-treatment of heartburn and dyspepsia to mild or moderate symptoms including postprandial burning in the upper abdomen or centralised abdominal discomfort.
➤ Refer patients with atypical or alarm symptoms (Table 14-2) for further evaluation.
➤ Refer children younger than 12 years with heartburn or dyspepsia to their primary care provider.
➤ Counsel patients with heartburn on nondrug measures such as dietary and lifestyle modifications (see the box Patient Education for Heartburn and Dyspepsia).
➤ Advise self-treating individuals of the advantages and disadvantages of various antacids and acid-reducing products so they can select a product that is best suited for them.
➤ Antacids provide temporary relief for mild and infrequent heartburn and dyspepsia.

REFERENCES

Getting Started

As the Project Coordinator, the first step to implementing a successful event is to schedule a meeting with your APhA-ASP Chapter Advisor, other interested faculty, and your APhA-ASP chapter officers to set tangible goals for your chapter to accomplish through Operation Self-Care. This meeting will give you an opportunity to discuss your ideas, brainstorm, and set the direction of your Operation Self-Care events. Preparation should begin at least 6 weeks before the patient care project occurs.

The process of recruiting students to participate should start early to increase the opportunities for participation. You can hold an interest meeting to outline projects and brainstorm. The interest meeting will offer you the opportunity to assess student interest and begin forming committees. Forming committees will increase involvement and encourage participation in future events. These committees can be responsible for areas such as promotion, advertising, training, documentation, and reports. Each committee will have specific tasks and responsibilities. These are just a few suggestions for committees, and can be adjusted as seen fit by the Project Coordinator. An example of the specific duties of each of these committees is outlined later in this section, and as stated above you can tailor the number and responsibilities of these committees to fit your chapter’s needs.

Project Organization

Screening days can be conducted throughout the year and can be held in conjunction with other events and patient care projects. Hosting multiple patient care projects at one time allows you to offer screenings for multiple disease states and better utilize the time of volunteers. Continue utilizing the Operation Self-Care Planning Guide materials and establish a timeline to facilitate your planned screening and education day.

Enlist the support of a faculty project advisor (e.g. either the APhA-ASP chapter advisor or another interested faculty member). Your faculty project advisor can assist you in coordinating a training session, and also be a supportive contact in case you encounter challenges during the project. The faculty project advisor will need to be well informed about the activities going on with the project in order to help ensure success.

Begin developing your media contacts in the community. Also contact your state pharmacy association to see if they are interested in becoming involved with your project. Allow yourself about 2 weeks to complete this portion, and do not forget to utilize your committees.

Pharmacist Recruitment & Initial Publicity

During this two week period, you will need to identify the pharmacists who are interested in participating. Meet with these individuals to discuss the campaign and review plans for implementation of the campaign. The pharmacists will need to be present on the day of the event and can assist
students if they have any questions. You may also want to consider reaching out to your APhA New Practitioner Mentor as a resource of Operation Self-Care events.

This is also the time to start contacting radio and TV show producers and send a “pitch” letter indicating you would like an interview to promote this community service project. A pitch letter is used to introduce yourself to an editor or producer and suggest story ideas. There is information about pitch letters and other media tools in the “Promotion” section of this planning guide.

Media Outreach and Supply Procurement

To ensure the success of your event, getting the word out to the public is a vital part of the project. You will make your big advertising push to the public starting about 3-4 weeks prior to the event. Get your posters and flyers out to the identified locations, and make follow-up phone calls to media outlets to arrange interviews. Get in touch with local newspapers, radio, and TV stations to inform them about your event and when it will occur. Invite the public to attend. Another great tool to reach patients is a radio public service announcement (PSA). Deliver the PSA to the public service director of the stations. Contact the venue to find out what supplies and equipment is available. Work with your committees to ensure that the appropriate supplies have been ordered to provide heartburn education and screening services to patients. Use new and innovative ways to reach your target audiences, such as your chapter website.

Final Preparation

Now that you are in the homestretch, keep in touch with media contacts, and distribute literature throughout the community. Send news releases to local newspapers if they are not planning to run a feature article on the project. Make enough copies of fact sheets, consent forms, surveys and all other documentation forms and handouts to be distributed at the screening site.

Help your faculty advisor organize a training session to review heartburn information and details about the screening. Have the faculty advisor refer to the introduction section to see the educational material provided. The training session can take place during your lunch hour or another time that is convenient for students participating in the event. Topics for the training session should cover an overview of the disease state, how students should interact with the patients, and basic presentation skills. The Operation Self-Care event is also a great time to help your patients fill out a Personal Medication Record along with their heartburn screening form to take home; the training session is a great time to familiarize student pharmacists with the form. Procter and Gamble has provided great resources that should also be introduced to students during this session so that they may refresh themselves on how to best screen, educate, and treat heartburn sufferers.
Day of the Project

Implement Operation Self-Care! Hand out the literature you have prepared, give the presentation, and screen participants. Radio stations should be running the PSAs as well as other advertisements. Newspapers should run stories covering your event during the week. TV interviews should discuss the event and invite the public. Be enthusiastic!

You are now prepared to increase public awareness about heartburn. The event is an extension of your recent media campaign, and gives you the chance to personalize the education to the public. Through presentations to groups and one-on-one patient counseling, student pharmacists will focus their efforts on those individuals at the event site. By utilizing the tools provided, student pharmacists can assist the patients in effectively treating and relieving their heartburn symptoms. Be sure to check out the health literacy resources on www.pharmacist.com/students.

Post Event Follow-Up and Report Submission

Send out “Thank You” notes to participants and supporters. Be sure to keep a reference log of all contact names and numbers to assist in future patient care projects. The log can be of great assistance to future project coordinators, and will also be useful for your other patient care projects. Complete a project report on your Operation Self-Care activities and send into APhA headquarters. Reports must be submitted electronically no later than July 15. Late reports will not be accepted for award consideration under any circumstance. Awards will be presented during the APhA-ASP Opening General Session at APhA Annual Meeting & Exposition. (See “Reporting Guidelines” for more details)
**Project Coordinator Checklists**

The checklists below are provided as an example for the Project Coordinator(s) to follow. The individual tasks can be assigned to committees and adjusted to fit the project’s needs. These timelines are suggestions and should be modified to fit the needs of your event(s) as necessary.

**Six Weeks to Target Date**

**Begin 6 weeks prior to target date, and allow 2 weeks to complete**

___ Hold a meeting with your APhA-ASP Chapter Advisor, faculty advisor, and chapter officers to discuss your goals for the event.

___ Hold a student interest meeting to overview projects and brainstorm on event dates and locations.

___ Select a target date, timeframe, and location.

___ Form working committees and outline the tasks of each for your specific needs.

___ Develop a list of names, addresses, phone numbers, fax numbers, and e-mail addresses of media contacts in your community.

___ Contact your state pharmacy association to participate in the campaign; place advertisements and articles describing the Operation Self-Care in your state pharmacy journal.

___ Contact P&G for Prilosec samples at 1-800-766-0495.

**Four Weeks to Target Date**

**Begin 4 weeks prior to target date and allow 2 weeks to complete**

___ Identify and meet pharmacists who will participate to discuss the campaign and review plans for implementation of the campaign.

___ Identify radio and TV show producers; send information on Operation Self-Care with a “pitch letter” indicating you would like an interview to promote this community service project.

___ Contact state/local health departments to inform them of Operation Self-Care and your planned activities.

___ Send out education and screening day sign-up sheets to students.
ACTION PLAN

___ Produce promotional flyers and a promotional display for the event site.
___ Identify a source for all equipment necessary for the event and order as needed.
___ Enlist a faculty member to perform a 1-hour basic training session for all participating student pharmacists.
___ Contact your APhA New Practitioner Mentor and invite them to participate in your event.

Two Weeks to Target Date

**Begin 2 weeks prior to target date and allow 1 week to complete

___ Distribute posters and flyers to event target locations (pharmacies, senior centers, community centers, grocery stores, office complexes, etc.) advertising when and where heartburn education screening services will be provided.
___ Make follow-up phone calls to radio and TV producers to arrange an interview to discuss the Operation Self-Care.
___ Send out a media advisory to local newspapers, radio, and TV stations.

One Week to Target Date

**Begin about 1 week prior to target date and allow 1 week for completion

___ Continue follow-up contacts and distributing flyers and posters throughout the community.
___ If local newspapers are not planning to run a feature article on the project, send a news release to them detailing the Operation Self-Care.
___ Make copies of fact sheets, consent forms, surveys, and all other documentation forms and handouts to be distributed at the screening site.
___ Remind participating students to wear lab coats, nametags, and professional attire to the screening event.

Operation Self-Care Event Day

___ Deliver equipment and have it set-up at least ½ hour before the event.
___ Hand out brochures, bag stuffers, information sheets, and other patient advocacy information on heartburn at the locations where heartburn education and screening services are being provided.
__ Radio stations should be running the PSAs as well as other Operation Self-Care advertisements all day.

__ Newspapers should run stories covering Operation Self-Care.

__ TV interviews should be aired, outlining Operation Self-Care and inviting the public to attend.

__ Assign someone to collect all documentation and assessment forms; complete the screening summary results form.

__ Clean up and return equipment as needed at the conclusion of the event.

**Post Event Follow-Up and Report Submission**

**Within one week after project**

__ Send out “Thank You” notes/letters to:

  __ All media outlets that covered/promoted the event
  __ All business locations that promoted the event
  __ Pharmacists and other health care professionals involved in the campaign
  __ Your school Dean, faculty, advisor, and other supporters
  __ State and local pharmacy associations that promoted the event

__ Complete a project report on your Operation Self-Care activities and send into APhA headquarters for award recognition judging. Reports must be submitted electronically to the FTP site no later than **July 15**. Late reports will not be accepted for award consideration under any circumstance.
Operation Self-Care—Committee Outline

Promotions Committee Assignments

Action Items:

1) Select committee chairperson.
2) Select committee members.
3) Assign committee tasks to members for action.

Specific Tasks:

1. Seek out support of state and local pharmacy associations and the state board of pharmacy.
   - Find out the names of key contact persons (i.e. executive director, president, etc.) and when the next organizational board meeting will be held. Ask to be placed on the agenda to inform the group of the Operation Self-Care campaign and ways in which they can assist your chapter.

2. Prepare an outline to present at these meetings.
   - Remember to tailor it to the target audience because each organization will likely play a different role.
   - Your state pharmacy association may provide names of pharmacists/pharmacies that are interested in participating in the Operation Self-Care campaign. Additionally, they may be able to provide publicity support through the association’s journal or newsletters.
   - The board of pharmacy should be made aware of your project plans to ensure compliance with all state pharmacy laws and regulations.
   - Compile a list of all contact persons identified in this step that can be shared with the advertising committee. Each of your key organization contact persons should be provided with copies of all consumer advertising materials and kept abreast of your promotion and event activities so as to maximize your support from these organizations.

3. Attend meetings and ask for support from these organizations.
   - It is your responsibility to make sure enough pharmacists are at the event, so make sure you have commitments from pharmacists to participate.
   - The event will require at least 2 pharmacists present at all times.
• The education presentation will take about 45 minutes. There is material which can be added or deleted to tailor the presentation to your chapter’s time constraints. Check the presentation guide for more details.

4. Meet with pharmacists and other health care professionals who have committed to assist with your project.
   • Provide more detail to them from the Operation Self-Care presentation and your project. Ask for their ideas and suggestions on how to make your project even more successful.

5. Encourage chapter members to participate.
   • Dedicate time at a chapter meeting early in the planning period to promote participation in Operation Self-Care to general members.
   • Ask interested members to sign up so that they can be included in the planning process.
   • Send out education and screening day sign-up sheets to the students 3 to 4 weeks before the event.
   • You will need enough students to counsel the patients with a reasonable waiting time. Each patient will need 5-10 minutes of one-on-one time with a student pharmacist. Try to get an estimate of patients attending and plan to have enough students to counsel. Remember to enlist enough student assistance for set-up (½ -hour before) and clean-up (½-hour after). Remind chapter members that providing patient counseling is a way to prepare for providing Medication Therapy Management as a licensed pharmacist.
   • Ask students to sign up to participate and provide them with the educational material included in Section 2 of this guide.
   • Only enlist students for education and screening shifts if they have completed training conducted by the training committee on the proper patient education/counseling techniques.

6. Educational preparation
   • One to two weeks before the event, organize a time with your faculty advisor to have a 1-hour informational session for all participating students, provide an overview of heartburn education and screening recommendations, and prepare the students to answer questions they may receive.
Operation Self-Care—Committee Outline

Advertising Committee Assignments

Action Items:

1) Select committee chairperson.

2) Select committee members.

3) Assign committee tasks to members for action.

Specific Tasks:

1. Keep in communication with the Promotion Committee.

   • Get a list of the people to contact at the state and local pharmacy associations, and board of pharmacy from the promotion committee.

   • Once the contacts have been established, begin to communicate with these organizations to learn of ways they may be able to assist you in getting the word out to the public about your Operation Self-Care event. For example, they may already have established contacts with local newspapers, radio, and television stations. Ask the organizations for their help advertising. They may be able to assist in preparing press releases or in getting ad placement in key newspapers.

2. Consult with pharmacists who have committed to be a part of your project.

   • The Promotion Committee should be able to provide you with the names of those who have committed. Ask these pharmacists for their assistance in brainstorming ideas for promotion of the event to the public.

   • These pharmacists may also be able to distribute bag stuffers or flyers with each prescription they dispense or with each front-end pharmacy sale. They may also be willing to post flyers or posters in their pharmacies as a way of promoting your upcoming event.

3. Produce promotional flyers.

   • A sample flyer is provided as a part of this packet. However, be sure to include the date, time and location(s) of your Operation Self-Care event(s).

   • Use brightly colored paper and large, bold lettering on your flyers to increase their visibility.

   • If pharmacies will be distributing the flyers as bag stuffers or at the checkout counter, be sure to provide an adequate supply to each pharmacy.

   • Your local or state pharmacy association, participating pharmacies, or school may be willing to assist with copying of the flyers to help offset expense.
4. Start posting flyers in the area of the site at least 2 weeks prior to the event.
   - If your education and screening site is a pharmacy or other retail outlet, be sure to provide an extra supply of flyers for distribution to every patient and customer of the store.

5. Work with pharmacy organizations to aggressively inform the media of the event.
   - Submit press releases, develop public service announcements for radio and TV stations, and arrange interviews with radio, newspaper, and TV reporters 1 - 2 months before your event if possible.
   - Try to get TV coverage on the day of your event by inviting local celebrities to take part in the Operation Self-Care education and screening day.

6. Continue to advertise on the radio and television all the way up to the day of the event.
   - Follow up regularly with the pharmacy organizations and the media to inform them of your progress. Keep trying, sometimes the media cannot commit until the last minute, and be prepared incase they show up without notice.

7. Create a promotional display
   - Create a promotion exhibit on a corkboard (bulletin board) or poster board to display at the site the day of the event to attract people passing by the event.
Operation Self-Care—Committee Outline

Site and Equipment Committee Assignments

Action Items:

1) Select committee chairperson.

2) Select committee members.

3) Assign committee tasks to members for action.

Specific Tasks:

1. Determine a location for the education and screening site.
   - The Promotion Committee should be able to provide contact information of pharmacists interested in participating in the event. The pharmacists should be consulted for recommendations of host sites.
   - Talk to faculty, local pharmacists that may not be participating in the event, and fellow students about any site that may be available for use.
   - You will need a site large enough to accommodate 3 to 4 tables, 10 student pharmacists, and 2 pharmacists at any given time during the education and screening event.
   - Adequate space for patients that does not interfere unnecessarily with the site’s business operations is also required, as well as for patient privacy.

2. Identify a source for all equipment necessary to perform your Operation Self-Care project and acquire equipment. Depending upon the nature of your event, additional items may be necessary and some recommended items may be unnecessary for your particular event.

Sample Checklist:

___ Four, 6-foot tables
___ 20 folding chairs
___ Pens, markers and pencils
___ Laptop computer
___ Projector for laptop
___ Projection screen
___ Power strip/electric extension cord
___ Blank Screening Documents
___ Blank Personal Medication Records
___ Brochures
___ Contact information for patients
___ Clipboards (4-6)
___ Tape to cover any extension cords
___ Patient education materials

3. Deliver equipment and set-up the day of the event. Tear down and return equipment at the conclusion of the event.
Operation Self-Care—Committee Outline

Training Committee Assignments

Action Items:

1) Select committee chairperson.

2) Select committee members.

3) Assign committee tasks to members for action.

Specific Tasks:

1. Consult with the Promotions Committee and find out the date of the event, as well as the names of all pharmacists who have committed to participate in the event. Find out the names of all students who have been enlisted to assist with the event.

2. Enlist a faculty member (either the chapter advisor or another faculty member) to perform a 1-hour basic training session for all participating student pharmacists.

   • Training should occur 1 to 2 weeks prior to the scheduled education and screening event. The faculty member should provide an overview of the education and screening tools, recommendations, how to help a patient fill out a personal medication record (this is Medication Therapy Management!), the presentation, and tips on giving a good presentation. Invite participating pharmacists to attend this brief educational session as well. This is a good opportunity to give a sample presentation and allow students to witness the correct way to use the materials supplied by the P&G.

3. Provide participating pharmacists with copies of all patient education materials that have been acquired by the Site and Equipment Committee.

   • Also provide the participating pharmacists with a listing of all students who will be participating in the event and information on the types of devices that will be used for screening. Determine from the pharmacist if he or she needs any additional information before the education and screening event.

4. Remind participating students to wear lab coats, nametags, and professional attire to the education and screening event.

   • This is for the purpose of projecting a professional image to patients, pharmacists, professional association representatives and media representatives that may be present for the event.
Operation Self-Care—Committee Outline

Documentation Committee Assignments

Action Items:

1) Select committee chairperson.
2) Select committee members.
3) Assign committee tasks to members for action.

Specific Tasks:

1. Photocopies.
   - Make at least 150 copies of the patient consent form and any other handouts.
   - Make at least 75 copies of the patient assessment form per education and screening/event location (refer to “Forms” section).
   - Make at least 75 copies of the personal medication record form per education and screening/event location (refer to “Forms” section).
   - Consult with participating pharmacists and the Advertising Committee to gauge whether additional copies beyond the recommended number may be necessary.
   - Make several copies of the patient assessment for the student pharmacists to keep for each education and screening/event location (enough for at least 75 patient screenings).

2. Assign someone to collect all documentation and assessment forms at the conclusion of the event (refer to “Forms” section).

3. Complete the screening summary results form (refer to “Forms” section) and submit the form with the Chapter Operation Self-Care Report. All reports are due to APhA headquarters by July 15, 2011.

4. Within 1 week, send thank you letters to:
   - Participating pharmacists
   - Participating/supporting faculty members and administration
   - Local supporters
   - Participating organizations (i.e. local and state associations)
   - Participating student pharmacists
   - Site host(s)
   - Media contacts that provided event coverage
Operation Self-Care—Committee Outline

Project Report Committee Assignments

Action Items:

1) Select a committee chairperson who will also serve as the person responsible for assembling the final report for submission to APhA headquarters.

2) Select committee members. The committee should be made up of one representative from all activity committees (i.e. Promotion, Advertising, Site and Equipment, Training, and Documentation Committees).

3) Assign committee tasks to members for action.

Specific Tasks:

1. Each representative from the aforementioned committees should provide the committee chair with details necessary to complete the chapter’s final project report to APhA headquarters.

2. Remember, your chapter will be considered for an award and recognition based upon the details provided in your report, so try not to leave any important details out of the report. Include photographs, copies of news clips, and supporting letters if possible. Please refer to the “Reporting Guidelines” for detailed submission instructions.

3. All reports MUST be submitted electronically via the APhA-ASP FTP site no later than July 15.

4. Reports that are received after July 15 will not be considered. There will be no exceptions.

5. All chapters that submit a report on time will receive a plaque of recognition.

6. Awards will be presented at the APhA Annual Meeting & Exposition.