Getting Documentation Right

While real estate's mantra is "location, location, location," a similar motto could be applied to doctors: "documentation, documentation, documentation."

Fast Facts

- *If you notice an error or omission in the medical record within a day or two, it's okay to correct the record with a late entry. Any changes after 48 hours should be made as an addendum. Page 84.*
- *Most offices have nonclinical staff to answer the phone. However, if economically feasible, it's better to have a nurse or other medically trained person take calls. Page 86.*
- *If given the choice, more than 50 percent of patients would choose a medical office that allows them electronic access to medical records and communication rather than a practice that didn't offer these services. Page 90.*

A well-documented, complete chart protects physicians against lawsuits, showing timely, legible entries that explain the reasoning leading to the diagnosis along with any applicable laboratory or consultation reports. Those reports should, of course, be read and signed by the physician, with necessary follow-up action taken.

If a chart looks sloppy or incomplete, a jury may surmise that the physician's care was the same. In some cases, a lost critical document can make the difference in a lawsuit—with the jury thinking the physician is covering something up.

Although documentation can make a big difference in the case

There's more to GERD than heartburn…

…other symptoms include regurgitation, belching & early satiety.

Recent research supports an association between BMI and GERD symptoms[1-4]

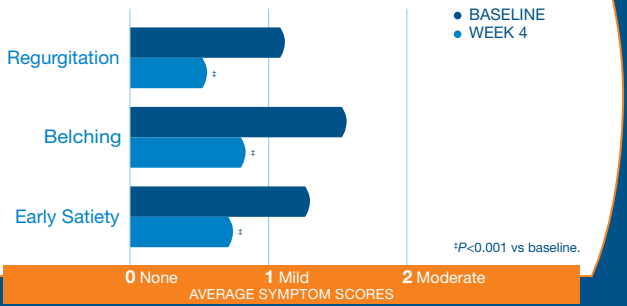
- Being overweight or obese is a risk factor for GERD symptoms[1]
- The risk doubles for patients who are overweight (BMI 25 to 30)[2]
- The risk triples for patients who are obese (BMI>30 to 35)[2]

GERD=gastroesophageal reflux disease

Write ACIPHEX to treat heartburn and beyond

Study design:
A combined analysis of 2 placebo-controlled studies (N=261) in nonerosive GERD patients with moderate to very severe heartburn who received ACIPHEX 20 mg once a day or placebo for 4 weeks (ITT: ACIPHEX, n=126; placebo, n=126)[5,6]

At 4 weeks, ACIPHEX significantly reduced severity of regurgitation, belching and early satiety*†[5]



*Symptom severity scores were recorded daily (0=none; 1=mild; 2=moderate; 3=severe; 4=very severe).
†Compared with placebo, at week 4 ACIPHEX significantly reduced severity of regurgitation (*P*=0.006),belching (*P*=0.007) and early satiety (*P*=0.04).

- Placebo: Regurgitation was reduced from 1.05 at baseline to 0.72 at week 4; belching was reduced from 1.47 at baseline to 1.06 at week 4; and early satiety was reduced from 1.28 at baseline to 0.91 at week 4. All *P* values were <0.001[5]

INDICATION
ACIPHEX 20 mg is indicated for the treatment of daytime and nighttime heartburn and other symptoms of GERD.

IMPORTANT SAFETY INFORMATION
In clinical trials the most common side effect assessed as possibly or probably related to ACIPHEX with a frequency greater than placebo was headache (2.4% vs 1.6% for placebo).

Symptomatic response to therapy does not preclude the presence of gastric malignancy. ACIPHEX is contraindicated in patients with known hypersensitivity to rabeprazole, substituted benzimidazoles, or to any component of the formulation. Patients treated with a proton pump inhibitor and warfarin concomitantly may need to be monitored for increases in INR and prothrombin time.

PLEASE SEE BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION FOR ACIPHEX 20 MG TABLETS ON FOLLOWING PAGE.

Manufactured and Marketed by
Eisai
Woodcliff Lake, NJ 07677

Marketed by
PriCara™
Unit of Ortho-McNeil Inc.
Raritan, NJ 08869-0602

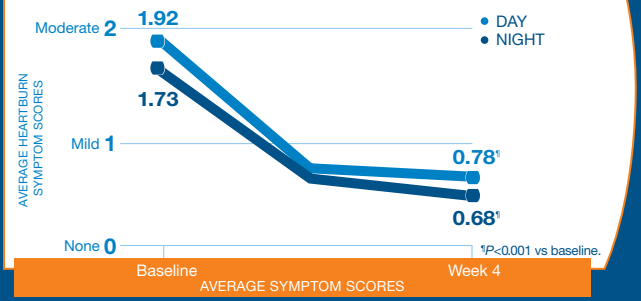
01AX1603D Sept. 2007

“There’s more to my life than GERD”

78%

of patients in these studies were overweight or obese (BMI≥25); however, BMI was not an enrollment criteria[5]

At 4 weeks, ACIPHEX significantly reduced nighttime and daytime heartburn severity[§‖5]



§Symptom severity scores were recorded daily (0=none; 1=mild; 2=moderate; 3=severe; 4=very severe).

‖Compared with placebo, at week 4 ACIPHEX significantly reduced severity of nighttime heartburn (P=0.006) and daytime heartburn (P<0.001).

- Placebo: Nighttime heartburn was reduced from 1.82 at baseline to 1.12 at week 4 and daytime heartburn was reduced from 2.01 at baseline to 1.33 at week 4. All P values were <0.001[5]

USA

PROUD PARTNER

TREAT HEARTBURN AND BEYOND

AcipHex®

rabeprazole sodium

References: 1. El-Serag HB, Graham DY, Satia JA, Rabeneck L. Obesity is an independent risk factor for GERD symptoms and erosive esophagitis. *Am J Gastroenterol.* 2005;100:1243-1250. **2.** Nilsson M, Johnsen R, Ye W, Hveem K, Lagergren J. Obesity and estrogen as risk factors for gastroesophageal reflux symptoms. *JAMA*. 2003;290:66-72. **3.** Hampel H, Abraham NS, El-Serag HB. Meta-analysis: obesity and the risk for gastroesophageal reflux disease and its complications. *Ann Intern Med*. 2005;143:199-211. **4.** Murray L, Johnston B, Lane A, et al. Relationship between body mass and gastro-oesophageal reflux symptoms: The Bristol Helicobacter Project. *Int J Epidemiol*. 2003;32:645-650. **5.** Data on file, Eisai, Inc. **6.** ACIPHEX full prescribing information.

The ACIPHEX Brand is affiliated with a Proud Partner of the U.S. Olympic Team.

AcipHex®
rabeprazole sodium
DELAYED-RELEASE TABLETS

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BRIEF SUMMARY
Before prescribing ACIPHEX®, please see full prescribing information.

INDICATIONS AND USAGE

Healing of Erosive or Ulcerative Gastroesophageal Reflux Disease (GERD)
ACIPHEX® is indicated for short-term (4 to 8 weeks) treatment in the healing and symptomatic relief of erosive or ulcerative gastroesophageal reflux disease (GERD). For those patients who have not healed after 8 weeks of treatment, an additional 8-week course of ACIPHEX® may be considered.

Maintenance of Healing of Erosive or Ulcerative Gastroesophageal Reflux Disease (GERD)
ACIPHEX® is indicated for maintaining healing and reduction in relapse rates of heartburn symptoms in patients with erosive or ulcerative gastroesophageal reflux disease (GERD Maintenance). Controlled studies do not extend beyond 12 months.

Treatment of Symptomatic Gastroesophageal Reflux Disease (GERD)
ACIPHEX® is indicated for the treatment of daytime and nighttime heartburn and other symptoms associated with GERD.

Healing of Duodenal Ulcers
ACIPHEX® is indicated for short-term (up to four weeks) treatment in the healing and symptomatic relief of duodenal ulcers. Most patients heal within four weeks.

***Helicobacter pylori* Eradication to Reduce the Risk of Duodenal Ulcer Recurrence**
ACIPHEX® in combination with amoxicillin and clarithromycin as a three drug regimen, is indicated for the treatment of patients with *H. pylori* infection and duodenal ulcer disease (active or history within the past 5 years) to eradicate *H. pylori*. Eradication of *H. pylori* has been shown to reduce the risk of duodenal ulcer recurrence. (See **CLINICAL STUDIES** and **DOSAGE AND ADMINISTRATION** in full prescribing information.)

In patients who fail therapy, susceptibility testing should be done. If resistance to clarithromycin is demonstrated or susceptibility testing is not possible, alternative antimicrobial therapy should be instituted. (See **CLINICAL PHARMACOLOGY, Microbiology** in full prescribing information and the clarithromycin package insert, **CLINICAL PHARMACOLOGY, Microbiology**.)

Treatment of Pathological Hypersecretory Conditions, Including Zollinger-Ellison Syndrome
ACIPHEX® is indicated for the long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison syndrome.

CONTRAINDICATIONS
Rabeprazole is contraindicated in patients with known hypersensitivity to rabeprazole, substituted benzimidazoles or to any component of the formulation.

Clarithromycin is contraindicated in patients with known hypersensitivity to any macrolide antibiotic.

Concomitant administration of clarithromycin with pimozide and cisapride is contraindicated. There have been post-marketing reports of drug interactions when clarithromycin and/or erythromycin are co-administered with pimozide resulting in cardiac arrhythmias (QT prolongation, ventricular tachycardia, ventricular fibrillation, and torsade de pointes) most likely due to inhibition of hepatic metabolism of pimozide by erythromycin and clarithromycin. Fatalities have been reported. (Please refer to full prescribing information for clarithromycin.)

Amoxicillin is contraindicated in patients with a known hypersensitivity to any penicillin. (Please refer to full prescribing information for amoxicillin.)

WARNINGS
CLARITHROMYCIN SHOULD NOT BE USED IN PREGNANT WOMEN EXCEPT IN CLINICAL CIRCUMSTANCES WHERE NO ALTERNATIVE THERAPY IS APPROPRIATE. If pregnancy occurs while taking clarithromycin, the patient should be apprised of the potential hazard to the fetus. (See **WARNINGS** in prescribing information for clarithromycin.)

Amoxicillin: Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients on penicillin therapy. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity and/or a history of sensitivity to multiple allergens.

There have been well-documented reports of individuals with a history of penicillin hypersensitivity reactions who have experienced severe hypersensitivity reactions when treated with a cephalosporin. Before initiating therapy with any penicillin, careful inquiry should be made concerning previous hypersensitivity reactions to penicillin, cephalosporin, and other allergens. If an allergic reaction occurs, amoxicillin should be discontinued and the appropriate therapy instituted. (See **WARNINGS** in prescribing information for amoxicillin.)

SERIOUS ANAPHYLACTIC REACTIONS REQUIRE IMMEDIATE EMERGENCY TREATMENT WITH EPINEPHRINE. OXYGEN, INTRAVENOUS STEROIDS, AND AIRWAY MANAGEMENT, INCLUDING INTUBATION, SHOULD ALSO BE ADMINISTERED AS INDICATED.

Pseudomembranous colitis has been reported with nearly all antibacterial agents, including clarithromycin and amoxicillin, and may range in severity from mild to life threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents.

Treatment with antibacterial agents alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is a primary cause of "antibiotic-associated colitis".

After the diagnosis of pseudomembranous colitis has been established, therapeutic measures should be initiated. Mild cases of pseudomembranous colitis usually respond to discontinuation of the drug alone. In moderate to severe cases, consideration should be given to management with fluid and electrolytes, protein supplementation, and treatment with an antibacterial drug clinically effective against *Clostridium difficile colitis.*

PRECAUTIONS

General
Symptomatic response to therapy with rabeprazole does not preclude the presence of gastric malignancy.

Patients with healed GERD were treated for up to 40 months with rabeprazole and monitored with serial gastric biopsies. Patients without *H. pylori* infection (221 of 326 patients) had no clinically important pathologic changes in the gastric mucosa. Patients with *H. pylori* infection at baseline (105 of 326 patients) had mild or moderate inflammation in the gastric body or mild inflammation in the gastric antrum. Patients with mild grades of infection or inflammation in the gastric body tended to change to moderate, whereas those graded moderate at baseline tended to remain stable. Patients with mild grades of infection or inflammation in the gastric antrum tended to remain stable. At baseline 8% of patients had atrophy of glands in the gastric body and 15% had atrophy in the gastric antrum. At endpoint, 15% of patients had atrophy of glands in the gastric body and 11% had atrophy in the gastric antrum. Approximately 4% of patients had intestinal metaplasia at some point during follow-up, but no consistent changes were seen.

Steady state interactions of rabeprazole and warfarin have not been adequately evaluated in patients. There have been reports of increased INR and prothrombin time in patients receiving a proton pump inhibitor and warfarin concomitantly. Increases in INR and prothrombin time may lead to abnormal bleeding and even death. Patients treated with a proton pump inhibitor and warfarin concomitantly may need to be monitored for increases in INR and prothrombin time.

Information for Patients
Patients should be cautioned that ACIPHEX® delayed-release tablets should be swallowed whole. The tablets should not be chewed, crushed, or split. ACIPHEX® can be taken with or without food.

Please see FDA-approved patient labeling in the full prescribing information.

Drug Interactions
Rabeprazole is metabolized by the cytochrome P450 (CYP450) drug metabolizing enzyme system. Studies in healthy subjects have shown that rabeprazole does not have clinically significant interactions with other drugs metabolized by the CYP450 system, such as warfarin and theophylline given as single oral doses, diazepam as a single intravenous dose, and phenytoin given as a single intravenous dose (with supplemental oral dosing). Steady state interactions of rabeprazole and other drugs metabolized by this enzyme system have not been studied in patients. There have been reports of increased INR and prothrombin time in patients receiving proton pump inhibitors, including rabeprazole, and warfarin concomitantly. Increases in INR and prothrombin time may lead to abnormal bleeding and even death.

In vitro incubations employing human liver microsomes indicated that rabeprazole inhibited cyclosporine metabolism with an IC_{50} of 62 micromolar, a concentration that is over 50 times higher than the C_{max} in healthy volunteers following 14 days of dosing with 20 mg of rabeprazole. This degree of inhibition is similar to that by omeprazole at equivalent concentrations.

Rabeprazole produces sustained inhibition of gastric acid secretion. An interaction with compounds which are dependent on gastric pH for absorption may occur due to the magnitude of acid suppression observed with rabeprazole. For example, in normal subjects, co-administration of rabeprazole 20 mg QD resulted in an approximately 30% decrease in the bioavailability of ketoconazole and increases in the AUC and C_{max} for digoxin of 19% and 29%, respectively. Therefore, patients may need to be monitored when such drugs are taken concomitantly with rabeprazole. Co-administration of rabeprazole and antacids produced no clinically relevant changes in plasma rabeprazole concentrations.

In a clinical study in Japan evaluating rabeprazole in patients categorized by CYP2C19 genotype (n=6 per genotype category), gastric acid suppression was higher in poor metabolizers as compared to extensive metabolizers. This could be due to higher rabeprazole plasma levels in poor metabolizers. Whether or not interactions of rabeprazole sodium with other drugs metabolized by CYP2C19 would be different between extensive metabolizers and poor metabolizers has not been studied.

Combined Administration with Clarithromycin
Combined administration consisting of rabeprazole, amoxicillin, and clarithromycin resulted in increases in plasma concentrations of rabeprazole and 14-hydroxyclarithromycin. (See **CLINICAL PHARMACOLOGY, Combination Therapy with Antimicrobials** in full prescribing information.)

Concomitant administration of clarithromycin with pimozide and cisapride is contraindicated. (See **PRECAUTIONS** in prescribing information for clarithromycin.) (See **PRECAUTIONS** in prescribing information for amoxicillin.)

Carcinogenesis, Mutagenesis, Impairment of Fertility

In a 88/104-week carcinogenicity study in CD-1 mice, rabeprazole at oral doses up to 100 mg/kg/day did not produce any increased tumor occurrence. The highest tested dose produced a systemic exposure to rabeprazole (AUC) of 1.40 µg•hr/mL which is 1.6 times the human exposure (plasma $AUC_{0-\infty}$ = 0.88 µg•hr/mL) at the recommended dose for GERD (20 mg/day). In a 104-week carcinogenicity study in Sprague-Dawley rats, males were treated with oral doses of 5, 15, 30 and 60 mg/kg/day and females with 5, 15, 30, 60 and 120 mg/kg/day. Rabeprazole produced gastric enterochromaffin-like (ECL) cell hyperplasia in male and female rats and ECL cell carcinoid tumors in female rats at all doses including the lowest tested dose. The lowest dose (5 mg/kg/day) produced a systemic exposure to rabeprazole (AUC) of about 0.1 µg•hr/mL which is about 0.1 times the human exposure at the recommended dose for GERD. In male rats, no treatment related tumors were observed at doses up to 60 mg/kg/day producing a rabeprazole plasma exposure (AUC) of about 0.2 µg•hr/mL (0.2 times the human exposure at the recommended dose for GERD).

Rabeprazole was positive in the Ames test, the Chinese hamster ovary cell (CHO/HGPRT) forward gene mutation test and the mouse lymphoma cell (L5178Y/TK+/-) forward gene mutation test. Its demethylated-metabolite was also positive in the Ames test. Rabeprazole was negative in the *in vitro* Chinese hamster lung cell chromosome aberration test, the *in vivo* mouse micronucleus test, and the *in vivo* and *ex vivo* rat hepatocyte unscheduled DNA synthesis (UDS) tests.

Rabeprazole at intravenous doses up to 30 mg/kg/day (plasma AUC of 8.8 µg•hr/mL, about 10 times the human exposure at the recommended dose for GERD) was found to have no effect on fertility and reproductive performance of male and female rats.

Pregnancy

Teratogenic Effects. Pregnancy Category B: Teratology studies have been performed in rats at intravenous doses up to 50 mg/kg/day (plasma AUC of 11.8 µg•hr/mL, about 13 times the human exposure at the recommended dose for GERD) and rabbits at intravenous doses up to 30 mg/kg/day (plasma AUC of 7.3 µg•hr/mL, about 8 times the human exposure at the recommended dose for GERD) and have revealed no evidence of impaired fertility or harm to the fetus due to rabeprazole. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers

Following intravenous administration of ^{14}C-labeled rabeprazole to lactating rats, radioactivity in milk reached levels that were 2- to 7-fold higher than levels in the blood. It is not known if unmetabolized rabeprazole is excreted in human breast milk. Administration of rabeprazole to rats in late gestation and during lactation at doses of 400 mg/kg/day (about 195-times the human dose based on mg/m^2) resulted in decreases in body weight gain of the pups. Since many drugs are excreted in milk, and because of the potential for adverse reactions to nursing infants from rabeprazole, a decision should be made to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

The safety and effectiveness of rabeprazole in pediatric patients have not been established.

Use in Women

Duodenal ulcer and erosive esophagitis healing rates in women are similar to those in men. Adverse events and laboratory test abnormalities in women occurred at rates similar to those in men.

Geriatric Use

Of the total number of subjects in clinical studies of ACIPHEX®, 19% were 65 years and over, while 4% were 75 years and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

ADVERSE REACTIONS

Worldwide, over 2900 patients have been treated with rabeprazole in Phase II-III clinical trials involving various dosages and durations of treatment. In general, rabeprazole treatment has been well-tolerated in both short-term and long-term trials. The adverse events rates were generally similar between the 10 and 20 mg doses.

Incidence in Controlled North American and European Clinical Trials

In an analysis of adverse events assessed as possibly or probably related to treatment appearing in greater than 1% of ACIPHEX® patients and appearing with greater frequency than placebo in controlled North American and European trials, the incidence of headache was 2.4% (n=1552) for ACIPHEX® versus 1.6% (n=258) for placebo.

In short and long-term studies, the following adverse events, regardless of causality, were reported in ACIPHEX®-treated patients. Rare events are those reported in ≤1/1000 patients.

Body as a Whole: asthenia, fever, allergic reaction, chills, malaise, chest pain substernal, neck rigidity, photosensitivity reaction. Rare: abdomen enlarged, face edema, hangover effect. *Cardiovascular System:* hypertension, myocardial infarct, electrocardiogram abnormal, migraine, syncope, angina pectoris, bundle branch block, palpitation, sinus bradycardia, tachycardia. Rare: bradycardia, pulmonary embolus, supraventricular tachycardia, thrombophlebitis, vasodilation, QTC prolongation and ventricular tachycardia. *Digestive System:* diarrhea, nausea, abdominal pain, vomiting, dyspepsia, flatulence, constipation, dry mouth, eructation, gastroenteritis, rectal hemorrhage, melena, anorexia, cholelithiasis, mouth ulceration, stomatitis, dysphagia, gingivitis, cholecystitis, increased appetite, abnormal stools, colitis, esophagitis, glossitis, pancreatitis, proctitis. Rare: bloody diarrhea, cholangitis, duodenitis, gastrointestinal hemorrhage, hepatic encephalopathy, hepatitis, hepatoma, liver fatty deposit, salivary gland enlargement, thirst. *Endocrine System:* hyperthyroidism, hypothyroidism. *Hemic & Lymphatic System:* anemia, ecchymosis, lymphadenopathy, hypochromic anemia. *Metabolic & Nutritional Disorders:* peripheral edema, edema, weight gain, gout, dehydration, weight loss. *Musculo-Skeletal System:* myalgia, arthritis, leg cramps, bone pain, arthrosis, bursitis. Rare: twitching. *Nervous System:* insomnia, anxiety, dizziness, depression, nervousness, somnolence, hypertonia, neuralgia, vertigo, convulsion, abnormal dreams, libido decreased, neuropathy, paresthesia, tremor. Rare: agitation, amnesia, confusion, extrapyramidal syndrome, hyperkinesia. *Respiratory System:* dyspnea, asthma, epistaxis, laryngitis, hiccup, hyperventilation. Rare: apnea, hypoventilation. *Skin and Appendages:* rash, pruritus, sweating, urticaria, alopecia. Rare: dry skin, herpes zoster, psoriasis, skin discoloration. *Special Senses:* cataract, amblyopia, glaucoma, dry eyes, abnormal vision, tinnitus, otitis media. Rare: corneal opacity, blurry vision, diplopia, deafness, eye pain, retinal degeneration, strabismus. *Urogenital System:* cystitis, urinary frequency, dysmenorrhea, dysuria, kidney calculus, metrorrhagia, polyuria. Rare: breast enlargement, hematuria, impotence, leukorrhea, menorrhagia, orchitis, urinary incontinence.

Laboratory Values: The following changes in laboratory parameters were reported as adverse events: abnormal platelets, albuminuria, creatine phosphokinase increased, erythrocytes abnormal, hypercholesteremia, hyperglycemia, hyperlipemia, hypokalemia, hyponatremia, leukocytosis, leukorrhea, liver function tests abnormal, prostatic specific antigen increase, SGPT increased, urine abnormality, WBC abnormal.

In controlled clinical studies, 3/1456 (0.2%) patients treated with rabeprazole and 2/237 (0.8%) patients treated with placebo developed treatment-emergent abnormalities (which were either new on study or present at study entry with an increase of 1.25 x baseline value) in SGOT (AST), SGPT (ALT), or both. None of the three rabeprazole patients experienced chills, fever, right upper quadrant pain, nausea or jaundice.

Combination Treatment with Amoxicillin and Clarithromycin: In clinical trials using combination therapy with rabeprazole plus amoxicillin and clarithromycin (RAC), no adverse events unique to this drug combination were observed. In the U.S. multicenter study, the most frequently reported drug related adverse events for patients who received RAC therapy for 7 or 10 days were diarrhea (8% and 7%) and taste perversion (6% and 10%), respectively.

No clinically significant laboratory abnormalities particular to the drug combinations were observed.

For more information on adverse events or laboratory changes with amoxicillin or clarithromycin, refer to their respective package prescribing information, **ADVERSE REACTIONS** section.

Post-Marketing Adverse Events: Additional adverse events reported from worldwide marketing experience with rabeprazole sodium are: sudden death; coma and hyperammonemia; jaundice; rhabdomyolysis; disorientation and delirium; anaphylaxis; angioedema; bullous and other drug eruptions of the skin; severe dermatologic reactions, including toxic epidermal necrolysis (some fatal), Stevens-Johnson syndrome, and erythema multiforme; interstitial pneumonia; interstitial nephritis; and TSH elevations. In most instances, the relationship to rabeprazole sodium was unclear. In addition, agranulocytosis, hemolytic anemia, leukopenia, pancytopenia, and thrombocytopenia have been reported. Increases in prothrombin time/INR in patients treated with concomitant warfarin have been reported.

OVERDOSAGE

Because strategies for the management of overdose are continually evolving, it is advisable to contact a Poison Control Center to determine the latest recommendations for the management of an overdose of any drug. There has been no experience with large overdoses with rabeprazole. Seven reports of accidental overdosage with rabeprazole have been received. The maximum reported overdose was 80 mg. There were no clinical signs or symptoms associated with any reported overdose. Patients with Zollinger-Ellison syndrome have been treated with up to 120 mg rabeprazole QD. No specific antidote for rabeprazole is known. Rabeprazole is extensively protein bound and is not readily dialyzable. In the event of overdosage, treatment should be symptomatic and supportive.

Single oral doses of rabeprazole at 786 mg/kg and 1024 mg/kg were lethal to mice and rats, respectively. The single oral dose of 2000 mg/kg was not lethal to dogs. The major symptoms of acute toxicity were hypoactivity, labored respiration, lateral or prone position and convulsion in mice and rats and watery diarrhea, tremor, convulsion and coma in dogs.

℞ only

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of a malpractice claim, that doesn't mean clinicians should chart with such a claim in mind. The number-one purpose of a chart is to track patients' signs and symptoms, diagnostic tests, and other details of care in order to ensure quality patient care. The chart should accurately and completely reflect the care provided, no matter what the patient's outcome.

"If you're doing a thorough job, you don't need to worry about what it would look like in court," says Vicki Bokar, RN, CPHRM, director of clinical risk management at the Cleveland Clinic. "The biggest mistake you can make is to document with the idea of outsmarting a lawyer some day."

She stresses avoiding short cuts during exams or with charting. For example, clinicians sometimes document tasks without actually doing them—such as a hospital nurse who charts that he turned the patient every two hours, but actually didn't. She cautions that those who check such an action off without performing it are liable for punitive damages in a lawsuit.

"That's the basis right there for punitive damages—altered or falsified records," she explains. "Punitive damages are often not covered by insurance companies."

Keep it Clean

Waldene Drake, RN, MBA, vice president of risk management and patient safety for Cooperative of American Physicians, Inc. (CAP-MPT) in Los Angeles, Calif., says that she advises doctors to keep their records clean so they can avoid having to explain their undocumented recollections. Without a clean record, "it's one more hurdle when you get to trial," she says. "If you have to explain why you didn't call the patient back, or explain this or that before talking about the medicine—even if the medicine was good—the jury gets tired of hearing excuses."

She explains that if the record is clean, the focus stays on the quality of care practiced, without having the jury distracted by lack of documentation.

Even the basics need to be well documented, according to Steven Selbst, MD, a Wilmington, Del., pediatric emergency room specialist and author of *Preventing Malpractice Lawsuits in Pediatric Emergency Medicine* (American College of Emergency Physicians, 1999). This includes vital signs and how the

physician arrived at the diagnosis. "Doctors used to write three lines, but they can't get away with that anymore," he says, noting that in the emergency department, anyone who sees the patient needs to chart his or her observations and also read what the nurses and other doctors wrote. "People have to read each other's notes," he says.

"Doctors used to write three lines, but they can't get away with that anymore," Dr. Selbst says, noting that in the emergency department, anyone who sees the patient needs to chart his or her observations and also read what the nurses and other doctors have written. "People have to read each other's notes," he says.

It's also important to check the record for accuracy. This means not only confirming information recorded by other clinicians, but also checking what the patient has written on intake or other forms. For example, when taking a history and looking over the patient's medications and allergies, physicians should double-check the information with the patient. "You can't imagine how many patients list their allergies under medications, or medications under allergies," says Lewis Sharps, MD, FACS, an orthopedic surgeon and president of Pennsylvania's PPIX insurance exchange. "Or they forget to list medication problems, or forget to list they're on a blood thinner."

Dr. Sharps notes that patients on multiple medications often don't remember what they're taking. "I recommend they bring in a list next time," Dr. Sharps says, adding that "we might not provide treatment until we know what's going on."

Dr. Sharps tells physicians to remind patients that they are their own first line of defense against errors. "You need to tell your patients there is no one who can protect them in healthcare unless they protected themselves first." he says.

He adds that patients often don't tell physicians about factors that may affect their condition. While physicians must ask about medications and lifestyle choices that could affect the outcome, Dr. Sharps stresses that the patients also have a personal responsibility to accurately disclose this information. As an orthopedic surgeon, Dr. Sharps has seen cases in which a patient scheduled for back surgery doesn't admit to smoking cigarettes, which can affect the healing process. "Then they get a nonunion and sue," he says.

If you notice an error or omission on a chart, be aware that alterations can be easy to spot and are difficult to defend in court. The difference between a late entry and an alteration might be determined by the jury. "You can make a late entry, but anything beyond 48 hours is going to be looked upon as something that was made not for clinical purposes but for litigation avoidance," says Scott Buchholz, JD, CPHRM, a healthcare attorney with Dummit, Briegleb, Boyce & Buchholz in San Diego, Calif.

It's ironic that physicians don't get paid for answering these phone calls, yet are exposed to additional malpractice risk whenever the phone rings. "The malpractice exposure is that you're providing free service and you're held accountable for that answer," Dr. Sharps reasons.

Mr. Buchholz says that it's amazing what a handwriting expert can find, determining the type of pen used, analyzing where a line begins, and questioning why an entry began in the middle or bottom of the page. He says that if a physician needs to do a late entry, he or she should do it, but also should remember that it might have to be explained at a deposition or in court. "When I say late entry, I'm talking about crossing out something and writing something there and dating and initialing it, not whiting it out or cutting it out. I would not recommend changing a record if it means you're changing the history of someone's treatment."

Waldene Drake agrees with the timeline for altering a record. "If a doctor dictates something, he or she has a few days to alter it because there's a mistake or he or she misspoke," she says. "But after that, it's an addendum."

Phone Messages

It's hard to imagine any doctor's office without a phone message system, but most existing systems could use improvement. Messaging systems vary from the simple—a two-ply carbon-copy phone message pad—to a phone system linked with electronic medical records.

The person taking the message needs to fill out the message completely, with the patient's name, date and time of call, the complaint or question, and any applicable timeline.

Phone messages and scheduling notes are part of the medical

records. The Cleveland Clinic's Vicki Bokar notes that while staff may have recorded symptoms the patient complained of during the phone call or scheduling, those symptoms may not be reflected otherwise in the patient's chart. And that could come back and bite the doctor. "We look at the entire thing when a lawsuit is coming, and it may implicate them," Ms. Bokar says.

Taking the message is only step one. The other part is handling it properly. There are frequently lawsuits in which the physician has no record of the phone call or the nursing staff never got in touch with the physician, according to Dr. Selbst.

A phone message should be treated like a lab report, according to Dr. Palmisano. "It can't be put away until the doctor initials it."

It's ironic that physicians don't get paid for answering these phone calls, yet are exposed to additional malpractice risk whenever the phone rings. "The malpractice exposure is that you're providing free service and you're held accountable for that answer," Dr. Sharps reasons. From a quality perspective, Dr. Sharps says the most important response to these phone calls is that the patient gets a sufficient answer.

If the doctor decides that the issue doesn't warrant an office visit, or isn't going to meet the patient in the emergency room, Dr. Sharps notes that the physician is still responsible to make sure the patient gets the recommended follow-up. While the overuse of emergency rooms contributes to the high cost of healthcare as well as long waits to see a clinician, it's better to refer the patient to the ER if there's any question. And, he advises physicians not to make the leap of faith that patients who are advised to go to the emergency room will actually go. "If the patient is told to go to the ER, call to see that he or she arrived," Dr. Sharps says.

Just as in an office visit, it's important to document everything discussed with the patient during the phone call, since patients may be so worried about their condition that they don't hear or remember everything the doctor said. "Documentation is essential. The timeline is essential, and the follow-up is essential," Dr. Sharps says.

Doctors taking calls while traveling should have a pad of paper or message pad handy in order to write down the information discussed, soon after the call. The call should be documented

just as a call in the office would be, noting the complaint, time, date, advice, and any other discussions or recommendations.

"You need to know when not to give advice, but to tell them [the caller] to be seen in the emergency room or the office," Dr. Selbst says. "If you're trying to manage a sick patient over the phone—that's risky without a physical exam. You don't get a complete history by telephone," he explains, noting that it's easier to get a full assessment looking at the patient.

For night and weekend phone coverage by non-physicians, the physician in charge of the practice should set forth criteria for how to handle certain situations, according to the Cleveland Clinic's Vicki Bokar. These should specify under what circumstances patients should be instructed to go to the emergency room, what is considered life-threatening, and what situations require physician judgment.

If the call is answered by a nurse, Ms. Bokar says they need to know they cannot give medical advice over the phone, especially if they don't know the patient. "They shouldn't give advice other than 'Call your doctor or go to the ER,' or you're establishing a duty [to act]," Ms. Bokar explains.

Dr. Selbst points out that the same is true for all clinicians. "You need to know when not to give advice, but to tell them [the caller] to be seen in the emergency room or the office," he says. "If you're trying to manage a sick patient over the phone—that's risky without a physical exam. You don't get a complete history by telephone," he explains, noting that it's easier to get a full assessment looking at the patient.

In the ideal situation the office has electronic medical records, so the staff member answering the call can pull up the patient's record during the call, according to Dr. Selbst. "You can enter the call right into the system—what you told them and what you heard," he says.

Attorney Buchholz notes that most offices have nonclinical staff to answer the phone. However, he advocates for a nurse or other medically trained person to take calls, if economically feasible. Either one is required to document the complete phone call, and in a legal case of "he said/she said," the nurse would look more legitimate on the witness stand than a receptionist.

Special training is imperative. Recognizing that debilitating illnesses could be mixed in among scores of common complaints in phone messages is an important consideration for any practice, but can be especially tricky with pediatric patients. "The number of phone records the pediatrician gets that are mundane, followed by a critical one, is huge," says Dr. Sharps.

Lab Reports

Systems for monitoring and filing laboratory and X-ray reports are crucial for every practice. "It's the age-old issue of what kind of tracking do you have of lab and ancillary services," says Gerald Hickson, MD, pediatrician and director of risk prevention at Vanderbilt University Medical Center, as well as associate dean for clinical affairs at the Center for Patient and Professional Advocacy. "If you don't have a good tracking system, it's just pay your [malpractice insurance] money and take your chances."

Dr. Hickson adds, "Organizations at a minimum should have electronic means to log in what labs are ordered, and someone has to be responsible for surveillance. You can't rely on patients to call you back, or on labs to get the reports back to you."

In addition to tracking what's ordered and whether the lab results come in, there's the responsibility of actually looking at the results. "When the report comes back to the office, what happens to the report?" asks Dr. Palmisano. "If it's put into the patient's file in the records room and then the only time it's noted is when the patient returns, that's a bad system, prone to great error because the patient may not return." He adds that if the patient doesn't return for a year and the original lab report showed possible lung cancer, that's a missed opportunity to save the patient, and it can lead to a negligence claim.

Dr. Palmisano notes that staff should not put the report inside the paper record, but rather should put it on top of the chart on the doctor's desk. The record should not be filed until the doctor reads and initials it.

While making the report available with the chart to review sounds like common sense, these instructions need to be made clear to all staff, including temporary workers. CAP-MPT's Waldene Drake tells of a physician who hired a student as a sum-

mer employee. The employee wasn't trained to put the reports with the charts on the doctor's desk for review. Instead she filed the reports inside the charts and put the charts away. When the office staff realized what happened, they closed the office for a day to go through every chart, to be sure all the reports had been reviewed and signed.

E-mail Correspondence

If given the choice, more than 50 percent of people would choose a medical office that allows them electronic access to medical records and communication over a practice that didn't offer these services, a *Wall Street Journal* Online/Harris Interactive poll found.

In the survey, three quarters of people said they wanted e-mail reminders about appointments, the ability to make appointments online, and the option to e-mail their physician. Yet only 20 percent of clinicians work in a place where patients and clinicians e-mail each other, according to a Medical Records Institute and Professional Risk Associates, Inc., survey.

From some doctors' perspectives, getting e-mail directly from patients is a better way to hear about the patient's concerns than phone messages and playing phone tag. The patient sends the information in his own words, rather than having a receptionist take a message, and the message can be returned at the doctor's convenience. A study published in the February issue of the Archives of Surgery showed that email contact between patient and surgeon improves communication.

But physicians need to be aware that, like phone messages and lab reports, e-mail messages are part of the medical record and can be used during a lawsuit. "Doctors need to know if you put it in an e-mail, it's discoverable," Dr. Selbst says. "Whatever you say to the patient in that e-mail can end up in court. Doctors have to be careful about what they say."

At the Cleveland Clinic, Ms. Bokar advises physicians to put copies of received and sent e-mails in the medical chart: "Our advice is to send that to the electronic chart by copy and paste, or print it out for the paper chart."

If physicians sharing an office aren't consistent with this practice, it can cause continuity-of-care issues, further exposing the

practice to risk and the patient to working with a doctor who has incomplete information.

Debra Best, MD, a medical instructor and pediatrician with Duke Children's Primary Care in North Carolina, says that in her practice some physicians use e-mail while others prefer not to. "I personally will use it with little questions that come up after a well exam," she explains. "If it's a question about dropping off a form, that kind of thing is fine. Most of us tell our patients if it's something pressing, call the nurse advice line."

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While Dr. Best does not proactively give out her e-mail address to patients, she said that at Duke, physicians frequently see their colleagues or their colleagues' children as patients, which blurs the line. "Certain providers may not have said it was okay to e-mail them, but because you're in the academic system, they can pull you up [on the e-mail system]."

When setting up an e-mail system, physicians need to think through how often and at what times they will check and respond to patient e-mails, and communicate that to the patients before giving out an e-mail address.

"I tell them I won't necessarily get back to them quickly," Dr. Best says, noting that it can be problematic if a patient e-mails her with an urgent question.

Dr. Best says she can't always respond to patient e-mails in a timely manner. "There are some days when I may have time to check e-mails between patients, but there are too many times I don't have time until lunchtime or the end of the day."

She says she's had colleagues who checked their e-mail at the end of the day, only to find an e-mail from a parent whose child should have been seen that day. "But now it's 6:30, so from a convenience standpoint, it would have been easier if they had [called and] come in to be seen."

Even though she doesn't officially give out her e-mail address

Most Adults Report Interest in E-mail and Other Patient-centered Technology…

A *Wall Street Journal* Online/Harris Interactive survey of 2,684 adults over age 18 revealed that a majority would like e-mail and other electronic access to their physicians' offices.

Question: Which of the following technologies would you like to have access to when seeking care from a doctor or hospital?

	Yes, Would Like (%)	No, Would Not Like (%)	Not Sure (%)
An electronic medical record to capture medical information	64	18	19
E-mail to communicate directly with my doctor	74	14	13
The ability to schedule a doctor's visit via the Internet	75	14	11
Receiving the results of diagnostic tests via e-mail	67	22	11
A home monitoring device that allows me to send medical information – like blood pressure readings or blood tests – to the doctor's office via the telephone or e-mail	57	21	22
Reminders via e-mail from my doctors when I am due for a visit or some type of medical care	77	13	9

Question: If you could choose between two doctors, but only one used the following types of information technology in his or her practice, how much would this influence your choice of doctors?

	A Great Deal/To Some Extent (Net) (%)	A Great Deal (%)	To Some Extent (%)	Not Much/ Not at All (Net) (%)	Not Much (%)	Not at All (%)	Not Sure (%)
An electronic medical record to capture medical information	54	18	36	34	17	17	12
E-mail to communicate directly with me or a family member	62	23	38	29	15	14	9

But Most Do Not Have Access

Question: To what extent do you use, or have access to, the following:	I use it now	It's Available to Me but I Don't Use it (%)	It is Not Available to Me (%)	Not Sure (%)
An electronic medical record to capture medical information	2	3	73	22
E-mail to communicate directly with my doctor	4	4	73	19
The ability to schedule a doctor's visit via the Internet	3	4	75	18
Receiving the results of diagnostic tests via e-mail	2	3	76	19
A home monitoring device that allows me to send medical information – like blood pressure readings or blood tests – to the doctor's office via the telephone or e-mail	2	3	76	19
Reminders via e-mail from doctors when I am due for a visit or some type of medical care	4	3	74	19

Note: Percentages may not add up to exactly 100% due to rounding.

Source: The Wall Street Journal *Online / Harris Interactive Health-Care Poll September 2006. Harris Interactive Inc. All rights reserved.*

to patients, she still puts an "out of office" auto-responder message on her e-mail when vacationing, directing patients with urgent health matters to the nurse triage phone.

While Dr. Selbst doesn't use e-mail at his emergency department, he notes that some hospitals send out lab results using a code system. As the child leaves the emergency department, the parents are given a code for their child's lab test. The parents are told that the lab result won't be ready for a few days, and that they'll receive an e-mail when it's complete. "I wouldn't say these systems are perfected or widely used," Dr. Selbst says.

But not all physicians want to communicate lab results to patients via e-mail. Harriet Borofsky, MD, Medical Director of Breast Imaging at Mills-Peninsula Women's Center in San

Mateo, Calif., finds that a phone call is still the best route to deliver information. "I never send patient results on the Internet," she says. "I don't think it's a good way of communicating with patients. I always call—a direct phone call—then you know they understand what you're saying."

The American Medical Association (AMA) guidelines on e-mail are an oft-cited standard for the community. The guidelines stress that e-mails should never replace the face-to-face or phone discussions between patients and physicians, but rather should be used to enhance these discussions. Patients should be alerted in advance as to which other clinicians or office staff members might have access to the e-mails.

The AMA suggests that physicians develop a timeline for how often they will reply to messages, and have guidelines for what issues the physician will accept over e-mail, such as prescription refills, appointments, and billing issues.

Patients should be told, in the e-mail policy and in an auto-response sent when an e-mail is received, that any urgent matter should be called in, rather than sent via e-mail. E-mail can be used as a teaching device as well, to send out links to disease or health information contained on the practice's Website or on outside Websites.

Privacy, of course, is a huge concern when sending out patient health information online. For this reason, some practices opt for secure e-mail systems, which may or may not be connected to an electronic health record system. For e-mail systems using a portal, patients log into the portal, which sends the messages using encryption. Some secure e-mail systems are rated for HIPAA compliance.

Dr. Best says she is most concerned about privacy issues when e-mailing unsecured e-mail addresses. "At least when you're logged in through Duke, you can flag it if it's patient-specific information," she says. "It's not secure if I'm sending it to your Hotmail account."

The American Academy of Family Physicians (AAFP) thinks that electronic records and communication are so important that they opened the Center for Health Information Technology (CHIT), which provides information and resources for physicians planning to computerize their medical practices. CHIT

director Steven Waldren, MD, MS, encourages physicians to use e-mail with patients, as long as it's done in a secure manner.

"You have to have a good policy and consent from the patient to sign off on as you push the medical data out to them," Dr. Waldren says. "You need that consent for HIPAA."

Dr. Waldren recommends that the office e-mail policy should describe what information is appropriate for e-mail, how quickly the physician will return messages, and the payment structure for using e-mails, if there is one. "There are different models out there—an executive model where [the patient] pays a fee for monthly access," he says. He notes that some physicians use a nominal transactional fee, and some use e-mail with patients at no cost.

Harriet Borofsky, MD, finds that a phone call is still the best route to deliver information. "I never send patient results on the Internet," she says. "I don't think it's a good way of communicating with patients. I always call—a direct phone call—then you know they understand what you're saying."

Before e-mailing a patient, the doctor should give a copy of the e-mail policy to the patient during an office visit, allowing the patient to sign a consent form if the physician doesn't use a secure e-mail method. If the physician has a Website, a copy of the e-mail policy should also be posted there. And the actual e-mail should include a disclaimer at the bottom, reiterating that if it's an emergency, the patient should call 911 and that it's not appropriate to e-mail about an urgent matter. A confidentiality statement should also be included, advising anyone who isn't authorized to read the e-mail to delete it.

For legal reasons, it's important to avoid giving advice over e-mail, especially if there isn't a preexisting physician/patient relationship. Answering an e-mail with advice might constitute a duty to the patient.

While some physicians are concerned about the increased workload of answering e-mails without compensation, many physicians who have implemented e-mail systems find that patients don't abuse it, and they haven't been deluged with extra work. Some even feel more connected with patients because it's an easy way to stay in contact between office visits.