Technology to Improve Patient Care

Although electronic health records and other technology centered in the physician's office get the most attention, other technological advances—including remote monitoring devices, cellphones, and PDA applications—are improving patient care and adherence.

Chapter in Brief:

- *A 2006 report by Insight Research, Boonton, N.J., forecasts that the nationwide healthcare telecommunications market will reach $8.1 billion by 2011 from just under $6.3 billion in 2006 and $6.9 billion this year.*
- *The Center for Information Technology Leadership (CITL) at Partners HealthCare System in Boston says if emergency departments, physician offices, nursing homes, and correctional facilities nationwide adopt sufficient telecommunications technology with a hybrid of live video and stored data, the healthcare system could save $4.28 billion a year.*
- *Technology is driving the emergence of personalized and predictive medicine, in which physicians can treat medical problems before symptoms arise and help ensure adherence to treatment through the use of mobile medical devices.*
- *Telemedicine brings advanced medical knowledge and capabilities to patients in rural areas or to those who cannot easily get to the physician's office for an in-person visit.*
- *Targeted online services will bring reliable health information to patients and speed up the delivery of patient safety information to physicians and consumers alike.*

TREAT HEARTBURN AND BEYOND

Prescribe ACIPHEX to relieve heartburn & other symptoms of nonerosive GERD—regurgitation, belching & early satiety, because...

TREAT HEARTBURN AND BEYOND AcipHex® rabeprazole sodium

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 REVERSE.

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

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Eisai
Woodcliff Lake, NJ 07677

Marketed by
PriCara
Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc.
Raritan, NJ 08869-0602

01AX1596D
Apr. 2008

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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Manufactured and Marketed by Eisai Inc., Woodcliff Lake, NJ 07677
Marketed by PriCara, Unit of Ortho-McNeil, Inc., Raritan, NJ 08869

200637MB Revised February 2007

At first blush, the system known as HEROS may look like any other ambulatory electronic health record (EHR), with its fields for demographic data, insurance information, medication and allergy lists, clinical documentation, and coding functions. But it is much more flexible—and portable—than the typical EHR. Because it was developed for a specialized population, HEROS (the "H" stands for "homeless") has fields for aliases and physical descriptors such as scars and tattoos and does not return an error if the address field is left blank.

People living on the street often don't want to give their name or other identifying information, explains James P. Turley, PhD, RN, associate professor of health information sciences at the University of Texas Health Science Center at Houston. The system is capable of recording patient encounters to which a name or other identifier can be added later. As they get to know a provider, homeless patients may open up and provide the type of information that most medical practices take for granted.

Dr. Turley, a registered nurse with a PhD in community health information, volunteers with Healthcare for the Homeless—Houston, a program that provides free preventive, sick, and chronic care to some of the more than 30,000 people who live on the city's streets. Rather than sending clinicians out to treat patients with no idea of an individual's medical history, Healthcare for the Homeless—Houston arms its practitioners with clinical decision support and specialized data-capture functions on tablet computers.

The city of Houston is building what will be the nation's largest municipal wireless Internet network across its sprawling downtown area, using a high-speed technology known as WiMax. Once that is up and running (testing has been delayed several times since late 2007), Healthcare for the Homeless—Houston clinicians will have not only data links to, but also live voice communication with, on-call doctors and the ability to call for an ambulance in an emergency without using their cellphones.

As good as this sounds, it represents just one of many cutting edges of an emerging boom in mobile, wireless, and remote technologies to help improve patient care.

A 2006 report by Insight Research, Boonton, N.J., forecasts that the nationwide healthcare telecommunications market will

reach $8.1 billion by 2011 from just under $6.3 billion in 2006 and $6.9 billion this year, with wireless services for physicians and hospitals representing the fastest-growing segment. Spending on wireless will more than double the forecast annual growth rate of 5.4 percent for telecommunications as a whole from 2006 to 2011, according to the report.

To be sure, this is a broad category; but the applications in healthcare seem limitless, and healthcare organizations of all stripes are embracing mobility.

Smartphones

In the past two years or so, PDAs and cellphones have converged, picking up BlackBerry-style mobile e-mail capabilities and incorporating high-speed Web access and music players along the way to bring legitimacy to an all-in-one category of handheld devices called smartphones.

The Diffusion Group, a consulting firm specializing in information technology, calls smartphones the "'black bag' of the new millennium." The Dallas-based company estimates that 49 percent of doctors used Internet-capable smartphones in 2006 and forecasts physician market penetration of smartphones to reach 70 percent by 2011.

Christine Chang, a New York-based healthcare analyst for the British research firm Datamonitor, is generally bullish on mobile devices because of their potential to break down the barrier that a computer in the exam room might create between physician and patient. She believes that Apple's decision in early 2008 to allow third parties to develop applications for the iPhone could lead to greater adoption of EHRs and clinical decision support.

"The iPhone stands out from the rest of the currently available devices because of its functionality, ease of use, and, quite

frankly, appearance," Ms. Chang wrote in a March commentary sent to clients. With a screen larger and with greater resolution than that of the typical PDA or smartphone, and with built-in Wi-Fi and cellular Internet connectivity, the iPhone can replace the standard cellphone, BlackBerry, pager, PDA, and tablet PC that a mobile physician might otherwise carry.

"With no little buttons to push, the iPhone's touch screen brings easy-to-use technology to even the most technophobic provider," Ms. Chang wrote. She also indicated that the ability to zoom in on images and move through screens easily would speed entry and retrieval of patient information.

"The iPhone's functionality is undisputed—as a phone, camera, media device, and Web browser all in one device—who needs anything else?" Ms. Chang asked rhetorically.

Steven Chang, MD, agrees. Dr. Chang, hardly a technophobe as a contributor to online consumer health site RightHealth (*www.righthealth.com*) while he is on leave from the family medicine residency program at Stanford University, could only be called an early adopter; he waited in line for hours on June 29, 2007, to be among the first to get their hands on the hottest consumer electronics product in recent memory.

The iPhone clearly met Dr. Chang's initial expectations, at least in terms of potential. But one thing bothered him: its inability to run the Epocrates reference database he has used since medical school. "When Apple first introduced the iPhone, they didn't open it up to outside developers," Dr. Chang explains. "I realized Epocrates wasn't going to be available right away."

Dr. Chang posted an online petition on a Silicon Valley blog called GeekNUZ (*www.geeknuz.com*) to demand that Apple open up the phone's operating system to outside developers and for Epocrates to create an iPhone version of its reference software. In September, Dr. Chang delivered more than 500 physician signatures to both companies.

In the past, Epocrates had taken its time responding to significant demand for a BlackBerry version of its comprehensive, subscription-based software, but is among the first group of companies writing programs for the iPhone and its phoneless companion, the iPod Touch. In fact, Epocrates was one of just five companies invited to present at Apple's March 6 kickoff

event for the iPhone Software Development Kit.

While Epocrates has not announced a release date for the iPhone-compatible version of its subscription product, Epocrates Essentials (a database of information on drugs, diseases, and diagnostic tests), the company already has optimized its free, online drug database for the Safari Web browser on the iPhone, and now has an "iPhone Compatibility" link right on its home page (*www.epocrates.com*). Epocrates also has said the iPhone

Take a Tablet

iMedica, a Carrolton, Tex., EHR and practice management vendor, has a program called "Take a Tablet," launched in February.

"We do a demo for the physician. If they like the application, we leave a tablet [computer] with them for 7 to 10 days," says iMedica president and CEO Michael Nissenbaum. "The 'Take a Tablet' promotion is evidencing that physicians really want to try an application, as opposed to being sold an application." Mr. Nissenbaum says the promotion not only has boosted sales for the company, it has also helped improve physician confidence in the portable computers.

The tablet's resemblance to a pad and pen ramps up the learning curve, he says. "[Physicians already] know how to use a tablet PC, and when they go see their first patients, there's not this uncomfortable 'How do I look at a patient? How do I work the application? How do I work the tablet?'"

This higher comfort level helps shorten the productivity slowdown that inevitably accompanies the conversion from paper to electronic records. "Of course, if you can get back to your normalized patient load, it's a higher revenue potential for you," Mr. Nissenbaum says.

The iMedica software works on laptop and desktop PCs as well, but is optimized for the tablet, which offers the option to use dictation, handwriting, clicking, or drag-and-drop to put in information. "We try to lower the barrier to how you want to use it. It's not as disruptive as physicians feel it could be," he says.

The doctor can set the computer to download all the information on all patients seen in the previous 90 days and scheduled for the next 90 days. "You actually walk around with your patient files, and it's constantly synching up with your server any changes in those files," Mr. Nissenbaum explains. "Think about going to a nursing home or hospital and having your tablet with you and being able to document everything on that, coming back, synching up, and it's there."

offering will be the first mobile version of its software to display medication images, thanks to the larger screen size and greater resolution than other PDAs and smartphones.

For example, the "Identify Drug" feature, which lets users search for drugs based on color, shape, and other markings, will include photographs and links to drug monographs. Epocrates likely will add this process to future releases of PC software, software engineer Glenn Keighley said at the Apple event.

"A lot of physicians have adopted mobile devices," Dr. Chang says, but usually only as a companion to more powerful desktop and notebook computers. "What the iPhone is getting into is the whole territory of the mobile physician."

Path to Personalized Medicine

In a keynote address to the 2007 Medical Group Management Association (MGMA) annual conference in Philadelphia, futurist Dr. James Canton said that predictive medicine, prevention, and health promotion would prevail in American healthcare by 2015, driven mostly by technology. "The path to personalized medicine is emerging today," he said.

"Predictive medicine will drive medicine below the symptom line," Dr. Canton said, opening up a field he called "post-genomic medicine," in which clinicians will be able to address potential health problems before they actually emerge. Currently we have what Dr. Canton called "real-time health IT visualization," such as CT scans. Future physician practices may feature a diagnostic viewing station with multiple high-definition screens instead of the traditional exam room, he says.

According to Dr. Canton, more and faster wireless services will create "pervasive mobility"—the kind of thing some iPhone boosters see coming soon. He also said new devices will become more prevalent as the medical device industry grows at an expected annual rate of 4.6 percent through 2015.

Other studies seem to support Dr. Canton's forecast.

In a report published early this year, Dallas technology research firm Parks Associates expects 3.4 million Americans 65 and older to have networked medical devices in their homes by 2012, up from just 100,000 in 2006, and says home health-monitoring products and services will be a $2.5 billion industry at

When these radio hosts say
"this one is for the ladies"
it takes on a whole new meaning.

Dr. Mazzullo

Lisa Mazzullo, MD, OB/GYN,
Feinberg School of Medicine,
Northwestern Memorial Hospital

&

Dr. Streicher

Lauren Streicher, MD, OB/GYN,
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the end of that period.

Forrester Research said in 2004 that home and personal health monitoring will explode from a $5 billion industry in 2010 to $34 billion by 2015. The report said remote health monitoring—sometimes called "healthcare unbound"—would reach 60 percent of patients discharged after long hospitalizations and 40 percent of chronically ill Americans by 2015. (In line with the Parks estimate, Forrester forecasts market penetration among seniors to be lower, at about 12 percent.)

"The tipping point will occur when payers like CMS, Kaiser, United, and Blue Cross see the long-term benefit of reimbursing consumers for these expenditures," Forrester senior analyst Elizabeth W. Boehm wrote then.

Forrester also said growth would remain flat through 2008, which seems to have been an accurate prediction, given that few major insurers have agreed to pay for such devices.

Mercy Medical Center in Cedar Rapids, Io., decided not to wait to acquire Honeywell HomMed Sentry telehealth monitors to install in the homes of certain patients with diabetes, congestive heart failure, chronic lung disease, and/or renal failure, even at a lease rate of $81 per month each. (The purchase price would be $3,800.) The first 15 monitors went out to patients around March 1; and Margie Pence, director of home care services for the hospital, says Mercy seeks to have 45 of the FDA Class II (hospital-grade) devices in place by the same time next year.

Each day, a patient with the monitor takes vitals, including weight, temperature, oxygen saturation, blood pressure, and heart rate. "If they're diabetic, it can check their blood glucose level," Ms. Pence says. Text or voice prompts walk users through each step, and the machine sends readings via phone line or wireless pager to computers at the hospital. Honeywell says the entire process takes about 3 minutes. The patient's physician sets parameters for each data point, and someone from the hospital will call if levels are abnormal or if the patient forgets to take regular measurements.

Even though Mercy has to absorb the cost, it may end up saving money in the long run by cutting down on "frequent fliers" to the emergency department. "The goal is really to help these patients avoid rehospitalization," Ms. Pence explains. "If they're

Smart Pillbox

All the technology in the world can't guarantee that patients will take medication as prescribed, but new "smart" pillbox technology at least can tell them when it's time for the next dose.

A device called Med-eMonitor, connected to drug databases via the Internet, provides on-screen and audible reminders, as well as warnings about potentially harmful interactions. It has dispensing compartments for up to five drugs to record when a pill is removed and report that information back to a doctor, nurse, or caregiver.

This type of automatic, active remote monitoring could be considered an outgrowth of more passive technologies like the medication tracking and reminder systems on several consumer Websites that require some sort of human intervention—entering data or printing a dosing schedule, for example—to work.

The manufacturer, InforMedix Holdings, of Rockville, Md., claims an 89.5 percent adherence rate in a test among 76 HIV patients. Average adherence to HIV drug regimens is less than 70 percent; and as many as a third of HIV-positive patients in the U.S. will miss at least one dose over a given three-day period, according to the company, so this technology is showing some early promise.

re-admitted within a month of discharge, the hospital loses money." But if they can stay out of the hospital, the patients are the true winners.

For this reason, physician groups are trying to help this kind of technology proliferate. The American College of Physicians (ACP) is developing electronic tools for physicians to help measure and improve quality as part of the "patient-centered medical home" project. ACP is applying $100,000 in unrestricted grants from the UnitedHealth Foundation and the pharmaceutical giant Pfizer. Others who signed the Joint Principles of the Patient-Centered Medical Home in March 2007 include the American Academy of Family Physicians, the American Academy of Pediatrics, and the American Osteopathic Association.

Telemedicine Advances

On February 27, 2008, an audiologist at New York University Medical Center remotely activated a cochlear implant of a patient in Kampala, Uganda—reportedly the first time the pro-

cedure had been performed over the Internet.

The Center for Information Technology Leadership (CITL) at Partners HealthCare System in Boston says provider-to-provider telehealth could save $4.28 billion a year if emergency departments, physician offices, nursing homes, and correctional facilities nationwide adopt sufficient telecommunications technology with a hybrid of live video and stored data. That figure does not even take into account inpatient telemedicine, teleradiology, home monitoring, or continuing medical education, which are all popular applications for telemedicine technology.

As with other forms of technology, CITL researchers believe the prevailing third-party reimbursement system that rewards face-to-face encounters with practitioners holds back progress toward widely available telehealth services. State-by-state licensing of physicians also limits the number of doctors willing to provide telemedicine services, CITL reports.

The reimbursement problem is less of an issue in a relatively closed system like the Veterans Health Administration (VHA), where telemedicine actually has become the primary means of care coordination and disease management.

The VHA has a three-pronged telemedicine effort, with general telehealth, home telehealth, and store-and-forward remote consultations. General telehealth links patients and specialists at VA clinics and hospitals, primarily for mental health, rehabilitation, endocrinology, and telesurgical services. In home telehealth, the emphasis is on treating and monitoring veterans with diabetes, chronic heart failure, chronic obstructive pulmonary disease, post-traumatic stress disorder, depression, and spinal-cord injuries.

Store-and-forward telehealth services—with data and images saved for later retrieval—generally are reserved for transmission of images from clinician to clinician, mostly for teleretinal imaging, teledermatology, telepathology, and wound care. Since the VA tends to treat many chronically ill veterans, there has been an emphasis on diabetes-related preventive services, particularly teleretinal imaging to screen for diabetic retinopathy. VA clinicians now handle 170,000 teleretinal imaging cases each year.

A home telehealth training center in Florida helps the organization develop and evaluate a workforce for home telemedicine

services. The VHA also has established a National Polytrauma Network to deal with the growing number of veterans in need of chronic rehabilitation services.

University of Arizona surgeon Rifat Latifi, MD, knows the value of remote trauma care in both financial and human terms. As director of telemedicine services for University Medical Center in Tucson, Ariz., he says it would cost $20,000 to transfer a trauma patient to the hospital from the remote town of Douglas 100 miles away, and the process would put the patient's life in jeopardy. Instead, the well-established network of the Arizona Telemedicine Program (ATP) cuts the expense, saves precious minutes, and prevents a risky transfer by allowing a trauma specialist to make a diagnosis and set a care plan from afar.

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(CITL says that the 2.2 million patients transported between emergency departments each year add $1.39 billion to the nation's healthcare costs; a fully implemented telehealth system could prevent 850,000 transfers and save $537 million a year.)

Since 1996, the ATP has helped connect small desert communities, poverty-stricken Native American reservations, state prisons, and other underserved sites with medical expertise in the urban centers of Phoenix and Tucson. More than 170 sites in Arizona and beyond—including some across the Mexican border—now belong to the network, which has handled upwards of 100,000 remote patient encounters and 300,000 cases of teleradiology since its inception. The ATP involves primary care physicians and more than a dozen specialties, including dermatology, wound management, and psychiatry. An educational component to the network has an archive of more than 10,000 hours of continuing medical education and grand rounds, available at the university, via the Internet and on public-access television in the Tucson area.

Telemedicine works well in more urban areas, too. In western New York state, a pediatric telehealth program called Health-e-Access has shown potential for reducing the need for low-income parents to take unpaid leave from work in order to tend to their children's health needs.

Over a period of two-and-a-half years, University of Rochester researchers studied attendance at five inner-city child-care centers and found that absenteeism declined by half when telemedicine services for diagnosis and treatment of common acute pediatric illnesses were available. Telemedicine had approximately the same effect on absentee prevention as seasonal conditions, according to research published in the May 2005 edition of the journal *Pediatrics*.

The study, funded by $330,000 in federal grants and another $150,000 from private sources, including the Robert Wood Johnson Foundation, is set to wrap up in August after nearly eight years of research. Health-e-Access relies on off-the-shelf computer equipment, digital stethoscopes, and digital still and video cameras to capture and transmit interactive audio and video. Some cameras have attachments for specific viewing of the ear, nose, throat, skin, and eyes.

In a survey of parents, 91 percent of Health-e-Access contacts for their children allowed them to stay at work; and 94 percent of problems managed by the telehealth network during the study period might otherwise have required a visit to a doctor or emergency department.

Information On Demand

Sometimes a search engine is all a doctor needs. Mayo Clinic family physician Dr. John W. Bachman has the Google toolbar at the top of his Web browser for quick recall of educational literature to print for patients and to copy into the EHR. Google works great for Dr. Bachman because he knows how to word his queries. A query on "mayo sinusitis" quickly brings up Mayo Clinic's consumer page for that condition.

But the average patient may not get such a targeted response.

Last September, Steven Krein, CEO of a nascent healthcare search engine called OrganizedWisdom (*www. organized wisdom.com*), showed about 500 people gathered at a conference

on interactive technologies in healthcare that the top result of a Google search on "what is melanoma" was a link to a questionable purveyor of pharmaceuticals and herbal remedies. Mr. Krein calls that "index spam."

The results may have been the consequence of a poorly worded query, but that often is how people search, and the algorithms that sort search topics are not built to weed out spammers. And because advertisers pay for prominent spots on major search engines, the most pertinent—or reliable—results are not necessarily the most visible.

But that is changing in part because both Google and Microsoft made inroads into health information. For example, Google has embedded a customized search engine for physicians into the e-Rx Now software offered free by the National E-Prescribing Patient Safety Initiative.

More significantly, both Google and Microsoft are testing information aggregation platforms, called Google Health and HealthVault, respectively. Google is partnering with the Cleveland Clinic, and Microsoft is working with the Mayo Clinic as they develop their products. Both offer secure storage and exchange of healthcare connectivity services on which to build personal health records. Since both companies are heavily involved in Internet search, search engines are also key parts of the two offerings.

The HealthVault search engine actually can seek out information based on health conditions. Clicking on "hypertension" may bring up links to MDConsult, American Heart Association, WebMD, and Medline Plus pages, and will also show related products for sale, like blood-pressure monitors.

Google CEO Eric Schmidt promises that Google Health will not include advertising. Instead, he hopes the health offering will drive traffic to other, ad-supported Google services.

Google has not disclosed many details about its product, but the Mountain View, Calif.-based Internet search leader has been building healthcare expertise since at least 2006. Google has been relying, mostly on a volunteer basis, on a small team of healthcare professionals to tag "approved" health content as part of Google Scholar, a service—still in "beta," or test, status after more than two years—for sorting academic literature.

Online Alerts

A system called the Health Care Notification Network (HCNN), publicly unveiled in March, is intended to speed up and ultimately replace the long-standing process of mailing drug and device warnings and recalls to healthcare providers.

"We're talking about moving patient safety online and out of the U.S. mail," says Nancy Dickey, MD, president of the Texas A&M Health Science Center, College Station, Tex. Dr. Dickey, a past president of the American Medical Association, is chair of the iHealth Alliance, the governing body of Medem, a physician connectivity service founded by national medical societies that is providing the technology for HCNN.

Dr. Dickey calls the network a "single, simple, organized source for all product-related safety information" that helps physician practices, hospitals, pharmacies, and other providers adhere to the FDA's stated preference to disseminate public information by e-mail and other electronic forms of communication. The agency has agreed to participate in the HCNN.

Others endorsing the project include the Medical Group Management Association, UnitedHealth Group, Aetna, and Health Care Service Corp., which runs Blue Cross and Blue Shield plans in Illinois, Texas, Oklahoma, and New Mexico. Medem CEO Edward Fotsch, MD, says there have been "discussions" with the Centers for Disease Control and Prevention and with the Department of Homeland Security to identify effective ways to alert health professionals in case of pandemic outbreak or incident of bioterrorism such as the 2001 anthrax attacks.

In addition to speeding up the notification process, the HCNN site, *www.hcnn.net*, adds "interactive bells and whistles" to help deliver "more robust information" to clinicians and their patients, according to Dr. Fotsch.

A typical HCNN screen contains the actual alert in the center column, formatted in the same fonts and colors the FDA recommends for paper notifications. The left-hand column has links for more information on the drug or device in questions—including images—as well as a link to enable the user to contact the manufacturer. The right side of the screen has suggestions on how care providers can notify patients about each alert, plus a link to the FDA MedWatch reporting program.

Doctors who have Web portals through Medem can elect to have HCNN alerts posted to their sites and can e-mail the information directly to patients with Medem's iHealthRecord personal health record, according to Dr. Fotsch. Users can choose to have the notifications sent to anyone within the practice. "I think routing to the office staff is important," says Dr. Fotsch.

Alerts will be tailored to specialties so practices are not overwhelmed with every notice for every device or drug. "Nothing will make people discard information faster than receiving a large number of irrelevant alerts," Dr. Dickey says.

There is no charge for healthcare providers to participate. "If you can get patient safety today on a free network, you're hard-pressed to wait two weeks [for a manufacturer to print and mail a paper alert]," Dr. Fotsch says.

Malpractice insurance carriers, through the Physician Insurance Association of America (PIAA), are supporting HCNN as an essential element of patient safety, and the Joint Commission has endorsed the effort. "I am asking our insured physicians to enroll in the HCNN and receive their FDA-related patient safety notifications online," says David Troxel, MD, medical director of the malpractice insurer The Doctors Company.

Dr. Troxel was not willing to commit to offering premium discounts for participating. As with EHRs, liability carriers want hard, actuarially sound evidence that technology reduces risk.