

# The Role of Technology

Quality measurement and improvement projects are only as good as their data—which is locked in patient records and billing forms. Unlocking it may take some investment but is likely to be worth it in the long run, especially as reimbursement starts to depend on demonstrable results.

## Chapter in Brief:

- ▲ *Electronic health records (EHR) systems make it easy to create lists of patients with certain chronic conditions, to generate alerts when patients are due for procedures, to aggregate clinical and demographic data, and more.*
- ▲ *Initiatives to encourage use of EHR systems are proliferating almost as fast as quality measurement projects. Both government and private industry groups are getting involved in the push towards electronic systems.*
- ▲ *The way the practice enters the data into the EHR system will affect how easily it can pull data used to measure quality. Since this same data may be used to determine reimbursement rates, it pays to think ahead.*
- ▲ *Pay-for-performance means that practices that efficiently employ technology to track and improve quality of care can see a return on their EHR investment.*
- ▲ *Even if you don't have an EHR system and you have no immediate plans to get one, you can still measure quality for either external or internal initiatives. By using a simple patient registry and improving claims data, you can more accurately monitor the quality of care rendered by the practice.*

## TREAT HEARTBURN AND BEYOND

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

TREAT HEARTBURN  
AND BEYOND **AcipHex**<sup>®</sup>  
rabeprazole sodium

**“There’s more to  
my life than GERD”**

20 Winning Seasons, 5 County Championships, 1 ACIPHEX tablet daily

*Frank Johnson*

GERD=gastroesophageal reflux disease  
Hypothetical representation of  
a patient with nonerosive GERD.

### INDICATION

ACIPHEX 20 mg is indicated for the treatment of daytime and nighttime heartburn and other symptoms associated with GERD in adults and adolescents 12 years of age and above.

### 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.

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**PriCara**<sup>®</sup>  
Division of  
Ortho-McNeil-Janssen  
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PLEASE SEE BRIEF SUMMARY OF  
FULL PRESCRIBING INFORMATION ON REVERSE.

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**ACIPHEX®**  
(rabeprazole sodium)  
Delayed-Release  
Tablets

**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 in adults and adolescents 12 years of age and above.

**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 (14.5)** and **DOSAGE AND ADMINISTRATION (2.5)** 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 (12.2)** 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**

**Hypersensitivity to rabeprazole**

Rabeprazole is contraindicated in patients with known hypersensitivity to rabeprazole, substituted

benzimidazoles or to any component of the formulation.

**Use of Clarithromycin and hypersensitivity to macrolide antibiotics**

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

**Concomitant use of Clarithromycin with pimozide and cisapride**

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 and hypersensitivity to penicillin**

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

**WARNINGS AND PRECAUTIONS**

**Clarithromycin use in pregnant women**

**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.)

**Anaphylactic reactions associated with antibiotic use**

**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 that 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 associated with antibiotic use**

**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*.

## **Presence of gastric malignancy**

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.

## **Concomitant use with warfarin**

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.

## **ADVERSE REACTIONS**

Worldwide, over 2900 patients have been treated with rabeprazole in Phase II-III clinical trials involving various dosages and durations of treatment.

Because clinical trials are conducted under varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

## **Clinical Studies Experience**

The data described below reflect exposure to ACIPHEX in 1064 patients exposed for up to 8 weeks. The studies were primarily placebo- and active-controlled trials in patients with Erosive or Ulcerative Gastroesophageal Reflux Disease (GERD), Duodenal Ulcers and Gastric Ulcers. The population had a mean age of 53 years (range 18-89 years) and had a ratio of approximately 60% male/ 40% female. The racial distribution was 86% Caucasian, 8% African American, 2% Asian and 5% other. Most patients received either 10 mg, 20 mg or 40 mg/day of ACIPHEX.

An analysis of adverse reactions appearing in  $\geq 2\%$  of ACIPHEX patients ( $n=1064$ ) and with a greater frequency than placebo ( $n=89$ ) in controlled North American and European acute treatment trials, revealed the following adverse reactions: pain (3% vs. 1%), pharyngitis (3% vs. 2%), flatulence (3% vs. 1%), infection (2% vs. 1%), and constipation (2% vs. 1%). The 3 long-term maintenance studies consisted of a total of 740 patients; at least 54% of patients were exposed to rabeprazole for 6 months while at least 33% were exposed for 12 months. Of the 740 patients, 247 (33%) and 241 (33%) patients received 10 mg and 20 mg of ACIPHEX, respectively, while 169 (23%) patients received placebo and 83 (11%) received omeprazole.

The safety profile of rabeprazole in the maintenance studies was consistent with what was observed in the acute studies.

Other adverse reactions that were seen in controlled clinical trials which do not meet the above criteria ( $\geq 2\%$  of ACIPHEX treated patients and  $>$  placebo) and for which there is a possibility of a causal relationship to rabeprazole include the following: headache, abdominal pain, diarrhea, dry mouth, dizziness, peripheral edema, hepatic enzyme increase, hepatitis, hepatic encephalopathy, myalgia, and arthralgia.

In a multicenter, open-label study of adolescent patients aged 12 to 16 years with a clinical diagnosis of symptomatic GERD or endoscopically proven GERD, the adverse event profile was similar to that of adults. The adverse reactions reported without regard to relationship to ACIPHEX that occurred in  $\geq 2\%$  of 111 patients were headache (9.9%), diarrhea (4.5%), nausea (4.5%), vomiting (3.6%), and abdominal pain (3.6%). The related reported adverse reactions that occurred in  $\geq 2\%$  of patients were headache (5.4%) and nausea (1.8%). There were no adverse reactions reported in these studies that were not previously observed in adults.

**Combination Treatment with Amoxicillin and Clarithromycin:** In clinical trials using combination therapy with rabeprazole plus amoxicillin and clarithromycin (RAC), no adverse reactions unique to this drug combination were observed. In the U.S.

multicenter study, the most frequently reported drug related adverse reactions 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 reactions or laboratory changes with amoxicillin or clarithromycin, refer to their respective package prescribing information, **ADVERSE REACTIONS** section.

### Postmarketing Experience

The following adverse reactions have been identified during postapproval use of ACIPHEX. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure: sudden death; coma, 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 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.

### DRUG INTERACTIONS

#### Drugs Metabolized by CYP450

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.

#### Warfarin

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. (See **WARNINGS AND PRECAUTIONS**).

#### Cyclosporine

*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.

### Compounds dependent on gastric pH for absorption

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.

Concomitant use of atazanavir and proton pump inhibitors is not recommended. Co-administration of atazanavir with proton pump inhibitors is expected to substantially decrease atazanavir plasma concentrations and thereby reduce its therapeutic effect.

### Drugs metabolized by CYP2C19

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-hydroxyclearithromycin. (See **CLINICAL PHARMACOLOGY, Combination Therapy with Antimicrobials (12.3)** in full prescribing information).

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

### USE IN SPECIFIC POPULATIONS

#### 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  $\mu\text{g}\cdot\text{hr}/\text{mL}$ , 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  $\mu\text{g}\cdot\text{hr}/\text{mL}$ , 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 <sup>14</sup>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<sup>2</sup>) 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

Use of ACIPHEX in adolescent patients 12 years of age and above for short-term treatment of GERD is supported by a) extrapolation of results from adequate and well-controlled studies that supported the approval of ACIPHEX for adults (see **CLINICAL STUDIES (14.1, 14.2, 14.3)** in full prescribing Information and **INDICATIONS AND USAGE**); b) safety and pharmacokinetic studies performed in adolescent patients (see **Pharmacokinetics, Pediatric (12.3)** in full prescribing information). The safety and effectiveness of ACIPHEX for the treatment of GERD patients <12 years of age have not been established. The safety and effectiveness of ACIPHEX for other uses have not been established in pediatric patients.

In a multicenter, randomized, open-label, parallel-group study, 111 adolescent patients 12 to 16 years of age with a clinical diagnosis of symptomatic GERD or suspected or endoscopically proven GERD were randomized and treated with either ACIPHEX 10 mg or ACIPHEX 20 mg once daily for up to 8 weeks for the evaluation of safety and efficacy. The adverse event profile in adolescent patients was similar to that of adults. The related reported adverse reactions that occurred in ≥ 2% of patients were headache (5.4%) and nausea (1.8%). There were no adverse reactions reported in these studies that were not previously observed in adults.

## 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.

## Gender

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

## 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.

## PATIENT COUNSELING INFORMATION

### How to Take ACIPHEX

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. (See **PATIENT COUNSELING INFORMATION (17)** in full prescribing information.)

For prescription only

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Manufactured and Marketed by

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If your practice doesn't have electronic records—and studies show that most U.S. physician practices don't yet—be aware that the day is coming when physicians who still work with paper charts will be at a substantial disadvantage in documenting the quality of their care and in getting paid for it.

“Payers aren't going to pay, and your costs will go up unless you can show that you're keeping people healthy,” says Glen Tullman, CEO of Allscripts, a practice management software vendor that sells financial or clinical systems to physicians and practices. “With an EHR, our customers can show you what percentage of their patients have had a prostate exam and what percentage have had mammograms, in real time. Imagine the amount of work it would be to gather that information from 50,000 paper files.”

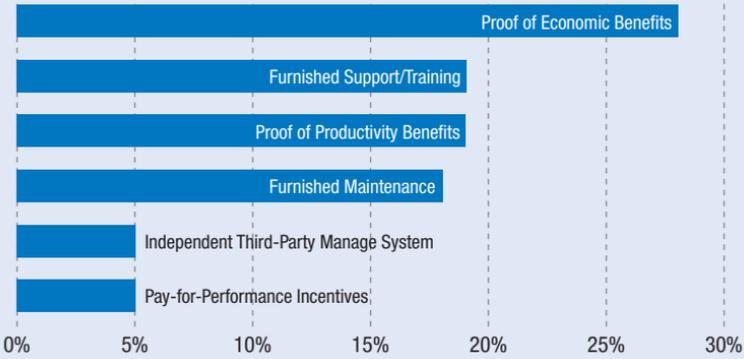
Practices that already have EHRs sometimes have to retrofit them to extract the correct data in correct form. With savvy shopping, practices that are just getting clinical automation for the first time will be able to demand what they need from their vendor in order to hit the ground running.

The American Academy of Family Physicians has been actively pushing electronic records for several years, and it estimates that 37 percent of family practitioners have an EHR system, while another 13 percent are in the process of implementing one. That's high—for physicians overall, the adoption rate for a comprehensive system is only 25 to 30 percent even in very large practices; and for physicians in solo practice, it's less than 10 percent, according to the Centers for Disease Control.

### **Costs and Benefits?**

Electronic records play a variety of roles in measuring and improving the quality of care. They can make it easy to create lists of patients with certain chronic conditions and alert the physician when certain tests or exams are due for each one. They can aggregate data, so that it's easy to see what percentage of hypertensive patients are being well controlled with medication, or what percentage of pediatric patients are current with their vaccinations. And if a practice is told by a payer, based on claims data alone, that it's not doing things that it should be doing (or is doing things it shouldn't), the EHR can provide a

## FACTORS INFLUENCING EMR ADOPTION



Source: GE Healthcare, Stark Physician Attitude Study Results, 2007.

way to check whether the allegation is accurate.

North Ohio Heart Center, which has four locations in the Cleveland area, has had an EHR system since 1994, making it one of the earlier adopters of the technology. “I have been shouted at because of [the system’s] limited functionality and dysfunctions. Now, if I shut the system off for 30 minutes, I get calls complaining about it,” says John Schaeffer, MD, president and chairman.

Although most payers’ pay-for-performance programs and other quality-checking activities are currently based on data from claims, Dr. Schaeffer finds the EHR a vital tool for confirming (or more often refuting) the accuracy of that data. “There’s a huge difference between claims and clinical data,” he says. “Most claims are a pittance of information. If I’m told I’m missing elements of vital care, I can prove them wrong 100 percent of the time” with the clinical data.

“EHRs have the potential to bring phenomenal, documentable quality and a significant improvement in safety,” Dr. Schaeffer says. “But it’s a very expensive ticket, and a lot of physicians simply can’t afford it.”

A study by the AAFP’s Center for Health Information Technology pegged the average cost of an EHR at about \$50,000 for a three-physician practice over three years, or about \$5,500 per

### “EMR” vs “EHR”

Although these terms are used interchangeably in places, there are some important distinctions: An EMR is a record of patient history and encounters within a single institution or organization. The term EHR historically has been reserved for something more encompassing, a full representation of a patient's medical history and health status across the continuum of care. A true EHR remains a future goal because full electronic connection between health systems does not yet exist in the United States.

physician per year. But the costs ranged from a low of \$3,000 to a high of more than \$130,000, depending on the complexity and abilities of the software, how much hardware was purchased, and how training and implementation were handled.

Initiatives to encourage EHR adoption are proliferating almost as fast as quality-measurement projects, and it pays to keep up with them. For example, the employer-funded pay-for-performance program Bridges to Excellence offers the Physician Office Link program, wherein physicians who treat a significant number of the participating employers' employees can get an incentive payment of \$50 or more for each of those patients for installing an EHR. (For more on how this works, and how it can pay off, see the case study on Four Seasons Pediatrics in Chapter 4.)

In June, the U.S. Department of Health and Human Services announced a demonstration project to provide financial incentives for EHR adoption to up to 1,200 primary care physicians in 12 areas (which can be either states or cities): Alabama; Delaware; Jacksonville, Fla.; Georgia; Maine; Louisiana; Maryland/Washington; Oklahoma; Pittsburgh; South Dakota; Virginia; and Madison, Wis. Physicians can receive up to \$58,000 each over five years (or a limit of \$290,000 per practice) for installing systems and using them to measure and improve quality of care. Selection of the practices will begin this fall.

### Stark Relaxation

Local hospitals may be another source of EHR funding. Until 2006, hospitals were forbidden to underwrite EHR costs for their affiliated physicians under federal anti-kickback rules, since

such help was seen as a potential bribe for referrals. Those rules, governed by the Stark Physician Referral law, were relaxed in 2006, as the federal government recognized that 1) electronic records would be a boon to the quality and efficiency of health-care and 2) many physicians were deterred from installing systems because of the formidable cash outlay involved. The new regulations allow hospitals to subsidize up to 85 percent of software and implementation costs although physicians still have to cover their own hardware. But with hardware getting cheaper and more powerful all the time, that expense can be relatively reasonable.

GE Healthcare, a major EHR vendor that markets the Centricity system for physicians' offices, did a study recently of how the Stark Relaxation, as it's known, might affect physicians' plans for EHR adoption. Across a sample of 200 physicians in practices of various sizes, the study showed that without the financial support made possible by the Stark Relaxation, only a third of physicians thought they could adopt or upgrade an EHR in the next year, and only 44 percent thought they could do it within three years. With the opportunity to have hospitals underwrite the cost, those percentages jumped to 57 percent and 62 percent.

But while having a hospital pay for the bulk of EHR costs might seem appealing, there are several potential pitfalls.

"The Stark Relaxation is a can of worms," says Margret Amatayakul, former associate executive director of the American Health Information Management Association and now a consultant who specializes in issues connected with EHRs. She says one problem is that if a delivery network supplies only its own EHR, the practice's data becomes commingled with that of other providers in the network, which is fine for practices owned by the network but problematic for those that aren't. "For patient care that's great; but if you decide to change your affiliation, you can't get your data out in any meaningful way," she says.

François de Brantes, CEO of the pay-for-performance program Bridges to Excellence, worries about giving hospitals too much control over the nation's overall health IT infrastructure. "Hospitals' kicking in is a very worrisome strategy, because it opens up a whole series of issues," he says. "If one hospital in an area controls the EHRs for all its physicians, it creates a huge

physician-hospital cartel that controls all medical records and can dictate whatever terms it wants.”

Steven Waldren, MD, director of the Center for Health Information Technology of the American Academy of Family Physicians, also counsels caution. “Hospitals are more likely to deploy technology that fits well with their system or is part of their system, so they may be offering records that aren’t in the best interest of outpatient primary care specialties,” he says. “You have to make sure they have the functionality and work flow that you need—otherwise the usability issues may cost you more than they’re giving you.”

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“Hospitals are more likely to deploy technology that fits well with their system or is part of their system,” says Bruce Bagley, MD. “You have to make sure they have the functionality and work flow that you need—otherwise the usability issues may cost you more than they’re giving you.”

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One strategy, though hardly a sure thing, is to wait until someone else—a payer, perhaps—decides that EHRs are important enough to underwrite the costs. That’s what happened in 2005 to physicians in three Massachusetts towns when the state Blue Cross Blue Shield plan decided to allocate \$50 million over three years to a program that would pay all their EHR costs.

More than 30 towns applied to be test sites, and three were chosen: Brockton, Newburyport, and North Adams. The grants included software, hardware, installation, training, and ongoing support through June 2008. The project involved 130 medical practices and 435 participating physicians (about 96 percent of all the physicians in the three towns); and of those, 417 had successfully adopted EHRs by April 2008. A survey conducted by the Massachusetts e-Health Collaborative, the not-for-profit organization overseeing the deployments, found that 86 percent of the participating physicians expect to provide higher-quality care with the EHRs.

The physicians were given a choice of seven different systems, all popular commercial products. The majority chose a product called eClinicalWorks. While many fretted about the

potential blow to their productivity during the transition, it was not as bad as they had feared: most had to cut their patient hours for only two-to-three weeks, and were back to full capacity within a month.

But it hasn't been entirely easy, even with the subsidy. For the first three or four months, physicians put in a lot of overtime at night entering their old data into the charts.

"We recommend that each practice come to an internal agreement about which prior data goes into the electronic chart," Micky Tripathi, president and CEO of MAeHC, says. Most practices enter the last two or three lab results, the last progress note, allergies, medications, and the problem list. They look ahead at who's coming to see them in the next week, and start the chart by typing in those four-to-six fields of data. Then they record their first progress note when they see the patient, and they're off and running. After three-to-five months, the same patients start to cycle back; and the number of new charts tapers off.

The failure rate for the project—the physicians who decide they just can't install EHRs successfully and abandon the whole idea—is one-to-two percent, compared with up to 20 percent among the larger physician population, according to a 2007 study by the Medical Records Institute.

The payoff for Blue Cross Blue Shield is coming in the form of a "data warehouse" that extracts certain pieces of information from the EHRs in real time and uses them to benchmark the quality of care. It's passive and automatic; the practices don't have to do anything. Currently the warehouse is collecting measures on coronary artery disease, diabetes, asthma, hypertension, prenatal care, and prevention. Only one community was submitting data as of May, although Mr. Tripathi expected to have all three running by the end of June. At that point he can start shopping the data around to health plans.

"The plans are very eager to see this because they get nothing right now," Mr. Tripathi says. He describes a conversation with a representative from a large, self-insured company who plows through reams of data every month derived from billing forms. "He said, 'I'm torturing claims data every which way, and I have no idea whether my employees are healthier.'"

## The Shopping List

No matter how a practice pays for an EHR system, it should be sure that whatever system it gets will be able to swap data with other providers it works with regularly, such as hospitals, laboratories, or imaging centers. That ability will be a boon to any project that uses continuity of care as a metric, because the record can then be structured to reflect all the services the patient received.

“You don’t want a custom-built integration,” says EHR consultant Cheryl Gregg Fahrenheitz, president of Preferred Healthcare Solutions, Bellbrook, Oh. “You should survey the area hospitals and see what their ambulatory solution is, and look for seamless integration with whatever product you choose.” She suggests making sure any EHR vendor already has partnerships with other products being used in the area. And vendors should be asked about whether and how data can be extracted for quality measurement projects, both internal and external.

GE Healthcare’s Centricity system, used by about 30,000 physicians, has an ever-growing central library of programs that it has developed to address the data-collection needs of various quality measurement initiatives, says CEO Brandon Savage. “If it’s not already built into the product, we take requests for reporting tools,” he says. “We’ve been hearing about these measures from potential customers, and we keep looking for ways that our product can help address those key performance factors without disrupting their practice.”

Once a system is chosen, experts recommend that a practice follow certain guidelines for data entry early on to ensure that the data can be extracted easily. They include the following:

- Enter the same data you want to pull out later. Don’t enter blood pressure as one value if a measurement project someday may want to see it as two.
- Enter as much data as possible in machine-readable form, rather than as scanned images of paper. Scanned images can’t be queried electronically, so the data they contain is no more useful for quality measurement than a paper chart.
- Keep free text to a minimum. Searching narratives for particular phrases is much more difficult for a computer than looking for specific fields and recording the values in them.



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- Make maximum use of check boxes, pull-down menus, and other strategies that limit the number of possibilities for a given piece of data. (However, don't sacrifice clinical accuracy in the process.)
- When entering data from paper charts, include all data points that you're tracking for quality. That way, for example, the system won't fire an alert to remind you to schedule a test that the patient has already had.

## EHRs: ROI?

Can EHRs pay for themselves? The answer is "sometimes," if a practice is focused on realizing the savings, and "almost certainly," once pay-for-performance permeates the market.

Central Utah Clinic installed its electronic health record system in 2002, and the savings it generated easily paid for the full cost by the end of 2003. The extra sums that will come from documenting quality of care for pay-for-performance initiatives are just gravy.

The clinic is spread out in 13 locations over 40 square miles of southern Utah, and is the only source of specialists south of Salt Lake City, says Jamie Steck, director of information technologies. He has an IT staff of eight.

The EHR system, from Allscripts, cost between \$1 million and \$2 million altogether: hardware, software, network, and peripherals, along with implementation and training. Mr. Steck's staff did a return-on-investment study that included only hard-dollar cost savings, and ignored squishy numbers like productivity increases or time savings. "Those are too subjective," he says. The hard savings included dictation costs, the salaries of no-longer-necessary chart room staff, the physical space of the chart rooms themselves (which were converted to revenue-generating clinical space), and the physical cost of creating a chart. Mr. Steck also threw in the measurable increases in revenue that resulted from the more accurate coding produced by the system. Altogether, the first-year savings were \$1 million, and the savings projected out to five years were up to \$10.5 million.

The EHR is a boon to quality measurement, both internally and for outside efforts like the Medicare PQRI program. Because they so easily could, Central Utah's physicians elected

to submit 74 indicators to PQRI rather than the minimum of three; and they included indicators for diabetes, congestive heart failure, coronary artery disease, and preventive services. Although the program had been going for several months before the practice starting submitting data, Mr. Steck expects to get between \$10,000 and \$12,000 for participating in the pilot phase, and says the reimbursement could have topped \$75,000 if Central Utah had participated fully for the entire year. Payers in Utah haven't embraced pay-for-performance; but when they do, the practice will be ready.

For its internal quality measurement effort, each specialty has chosen a specific common condition to measure—gastroesophageal reflux disease for the gastroenterologists, congestive heart failure for the cardiologists, diabetes and hypertension for the internists. Although the project is in its early stages, the physicians are already reporting improvements on some measures. “We can get the feedback to the physicians that these patients are out of compliance on these measures, so that the physicians can see what they need to do,” Mr. Steck says.

### **Quality Measurement Without an EHR**

Even if you don't have an EHR system and you have no immediate plans to get one, you can still measure quality for either external or internal initiatives. There are two tools that can get you started:

**Registries.** Projects that focus on chronic care can begin with a simple list of patients who have the condition being studied, along with columns for recording services they receive and test results. It's more streamlined to have registries as part of an EHR, but they can be maintained separately on a computer or even on paper, says Marie Schall, director of the Institute for Healthcare Improvement, which works with practices in all stages of clinical automation.

Family practitioner David D. Ortiz, MD, tracks diabetic patients in his San Antonio, Tex., practice with a simple Excel spreadsheet. His article in the April 2006 issue of AAFP's *Family Practice Management* describes how to use it, and the Web version includes a link to download it. There are also many commercial tools available for creating patient registries. (See

## Smart EHR Shopping

If you're shopping for an EHR system with quality data reporting in mind, you should get to know the Certification Commission for Healthcare Information Technology, or CCHIT ([www.cchit.org/](http://www.cchit.org/)). It was formed in July 2004 by the American Health Information Management Association, the Healthcare Information and Management Systems Society, and the National Alliance for Health Information Technology.

CCHIT's mission is to see that EHR products—both inpatient and outpatient—adhere to a certain set of standards, so that providers can count on a minimum level of performance and functionality no matter which product they pick. For 2007, CCHIT had 46 pages worth of standards for ambulatory record products. On page 38, it specifies, "The system shall provide the ability to generate reports of clinical and administrative data using either internal or external reporting tools" and notes, "Needed for pay-for-performance, quality improvement activities. All data that is entered in a structured format should be individually reportable."

Visit [www.doctorsdigest.net](http://www.doctorsdigest.net) for a list of products that have been certified as adhering to CCHIT's 2007 Ambulatory EHR standard.

Resources for a link to the article.)

**Better claims data.** Pay-for-performance programs that originate with payers, including Medicare and private insurers, almost always depend on claims data. As noted in Chapter 1, claims data can be a very poor reflection of what actually happened to the patient, especially over time; but there are things you can do to improve its accuracy.

Consultant Margret Amatayakul recommends hiring a coding expert to do an audit, with an eye toward data accuracy. "A lot of physicians don't know what code to put on a lab order, so they put something really broad like 'rule out disease,'" she says.

Lack of space is the bane of accuracy for many claims, says Cheryl Gregg Fahrenholz. A CMS 1500 claim form holds only four diagnosis codes and six CPT/HCPCS procedure codes, and a practice can fill those quickly for a patient with chronic conditions. If there's spillover, Ms. Fahrenholz recommends submitting two claims for the same date of service, if your billing system lets you, to be able to fit up to 8 diagnosis codes and 12

procedure codes. Make sure the diagnosis codes appear on the same form as their corresponding procedure codes.

If you're participating in the PQRI program, be sure the claims are split in such a way that neither of them shows charges of zero—otherwise the PQRI data may be rejected. As for gathering the PQRI data to begin with, Ms. Fahrenholz recommends incorporating quality codes into the charge slip, either in a separate space or in between existing lines. Another option is to develop a separate sheet to accompany the charge slip in the paper flow. "This way is best for practices that already have a lot of CPT and HCPCS codes on the charge slip," she says.

If payers doing quality measurement complain that you're not providing needed services, work with them to see whether there are mistakes in their claims analysis, suggests Ms. Amatayakul. She's seen as much as a 20-percent variation between the information a physician submits and the information the payer releases.

Increased communication can also help. "Providers and payers have such an adversarial relationship that they don't think to talk to each other."