Primary Care Model Gains Momentum

The medical home is built on the idea of patient-centered care in which physicians can focus on patients and not patient volume. While primary care physicians have supported the concept for a while—and may already be adopting it informally—the concept is only now gaining steam as government and other payers search for an approach that will make primary care more effective, more accessible, and more affordable. Nothing less than the future of primary care may lie in the balance.

Chapter in Brief:

- *The medical home changes the role of the primary care physician. But unlike the old "gatekeeper" days, this time it's voluntary, patients don't need permission to see specialists, and physicians generated the concept.*
- *Statistics show that primary care has diminishing appeal among internal medicine residents. The medical home may stimulate a turnaround by emphasizing a team approach to care, with more time for physicians to focus on patients, and increased compensation.*
- *Major efforts underway include TransforMED, an American Academy of Family Physicians (AAFP) subsidiary, and the Patient-Centered Primary Care Collaborative (PCPCC), which is supported by major medical associations. Medicare is also testing the concept.*

Denis Chagnon, MD, a family physician in Latham, N.Y., had an 88-year-old patient with an array of problems: diabetes, obesity, coronary disease, and chronic renal

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

INDICATIONS

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

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

As with all PPIs, patients treated concomitantly with warfarin may need to be monitored for increases in INR and prothrombin time, which may lead to abnormal bleeding and even death.

In adolescents, the related reported adverse reactions that occurred in ≥2% of patients were headache and nausea. The adverse reactions reported without regard to relationship to ACIPHEX that occurred in ≥2% of patients were headache, diarrhea, nausea, vomiting, and abdominal pain.

In adults, clinical trials revealed the following adverse reactions appearing in ≥2% of ACIPHEX patients and with a frequency greater than placebo: pain, pharyngitis, flatulence, infection, and constipation.

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

ACIPHEX inhibits gastric acid secretion and may interfere with the absorption of drugs where gastric pH is an important determinant of bioavailability (e.g., ketoconazole, iron salts and digoxin).

ACIPHEX may reduce the plasma levels of atazanavir.

Rabeprazole has been shown to inhibit cyclosporine metabolism *in vitro*.

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 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 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 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 PI}.

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 PI 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 ≥ 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 (≥ 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 ≥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 ≥ 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-hydroxyclarithromycin. {See ***CLINICAL PHARMACOLOGY, Combination Therapy with Antimicrobials* (12.3)** in full PI}.

Concomitant administration of clarithromycin with pimozide 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 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

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 PI and ***INDICATIONS AND USAGE***}; b) safety and pharmacokinetic studies performed in adolescent patients {see ***Pharmacokinetics, Pediatric*** **(12.3)** in full PI}. 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 PI.}

For prescription only

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disease. “He was kind of stable but not doing great, and he knew he was in his last year or two,” Dr. Chagnon says. One day the patient had a strange feeling in his chest and called 911. The paramedics brought him to a hospital where Dr. Chagnon doesn't admit. A physician there diagnosed him with a mild heart attack, then decided to do an angiogram when he couldn't find a pulse in his foot. That procedure put him into kidney failure. A kidney specialist started him on dialysis. After ten days of dialysis, a vascular surgeon did a bypass to try to save his leg. The procedure failed, and the leg had to be amputated. By the time the patient saw Dr. Chagnon a couple of months later, he'd been in and out of rehab and a nursing home, and was on dialysis and wheelchair bound.

“He sat there and cried,” Dr. Chagnon says. “He said, 'No one ever asked me if I wanted this. I've lived my life. If I'd known all this was going to happen, I would have told them not to start.'” After Dr. Chagnon assured him that he didn't have to stay on dialysis if he didn't want to, he discontinued it. He died at home three weeks later. “That's all the poor man wanted to begin with,” Dr. Chagnon says. “His care cost the system half a million dollars. No one did anything wrong, but no one really had a relationship with the patient or communicated with him about his wishes.”

Although the U.S. spends twice as much as any other developed country on its healthcare, such stories are all too common. And it's understandable, given the present payment system and its incentives. Because physicians are paid per encounter, per test, and per procedure, they naturally compensate for shrinking payments by squeezing more encounters, tests, and procedures into each day. Patients’ “oh, by the way” comments that stretch a 15-minute appointment into 20 or 30 without any hope of extra compensation become a moral dilemma. Talking with patients, which should be the glue that cements the doctor-patient relationship, instead becomes an obstacle to a more financially productive day. Even though primary care physicians choose their specialty because they want to build long-term relationships with their patients, it doesn’t always happen. And everyone suffers: the patients, the physicians, and a healthcare system that ends up spending billions on redundant or unwanted treatments.

Defining a Medical Home

What is a medical home? In March 2007, the American Academy of Pediatrics (AAP), the American College of Physicians (ACP), the American Academy of Family Physicians (AAFP), and the American Osteopathic Association (AOA) as part of the Patient-Centered Primary Care Collaborative (PCPCC) developed principles that included the following:

1. Personal physician: Each patient has an ongoing relationship with a personal physician trained to provide first contact and continuous and comprehensive care.

2. Physician-directed medical practice: The personal physician leads a team of individuals at the practice level who collectively take responsibility for the ongoing care of patients.

3. Whole-person orientation: The personal physician is responsible for providing all the patient's healthcare needs or taking responsibility for appropriately arranging care with other qualified professionals. This includes care for all stages of life: acute care, chronic care, and preventive services, as well as end-of-life care.

4. Care is coordinated and/or integrated across all elements of the complex healthcare system (e.g., subspecialty care, hospitals, home health agencies, and nursing homes) and the patient's community (e.g., family, and public and private community-based services). Care is facilitated by registries, information technology, health information exchange, and other means to assure that patients get the indicated care when and where they need and want it in a culturally and linguistically appropriate manner.

5. Quality and safety are hallmarks of the medical home, including having patients actively participate in decision-making, using information technology to support optimal patient care, and enhanced communication. Practices go through a voluntary recognition process by an appropriate non-governmental entity to demonstrate that they have the capabilities to provide patient-centered services consistent with the medical home model.

6. Enhanced access to care is available through systems such as open scheduling; expanded hours; and new options for communication among patients, their personal physician, and practice staff.

7. Payment appropriately recognizes the added value provided to patients who have a patient-centered medical home. It should pay for services associated with coordination of care both within a given practice and among consultants, ancillary providers, and community resources; support adoption and use of health information technology for quality improvement; support provision of enhanced communication access such as secure e-mail and telephone consultation; recognize the value of physician work associated with remote monitoring of clinical data using technology; allow for separate fee-for-service payments for face-to-face visits; recognize case-mix differences in the patient population being treated within the practice; allow physicians to share in savings from reduced hospitalizations associated with physician-guided care management in the office setting; and allow for additional payments for achieving measurable and continuous quality improvements.

For more information, see *http://www.pcpcc.net/content/joint-principles-patient-centered-medical-home*.

No Place Like Home

In a medical home, patient care is not always associated with the office visit. A patient visit could just as easily take place by way of phone, e-mail, or text message, through a group education session, or even by an occasional house call. Most routine care—immunizations, sore throats, school physicals—moves to nurses, medical assistants, or case managers. As a result, physicians now can focus their time, energy, and clinical insight on complex situations that make the most of their training.

The medical home is not an entirely new concept. In fact, medical home-like care is the standard in countries like Denmark that have national health insurance. "We know that countries with a strong foundation of primary care have better outcomes, lower costs, and greater equity," says Melinda K. Abrams, assistant vice president at the Commonwealth Fund and director of its Patient-Centered Primary Care Program (see *http://www.commonwealthfund.org/Content/Program-Areas/High-Performance-Health-System/Patient-Centered-Primary-Care-Initiative.aspx.)*

Even in the U.S. the term "patient-centered medical home"

has been around since the AAP elucidated it in 1967 in its principles for special-needs children, although it gained more traction when the AAFP put out its "Future of Family Medicine" report in 2004. Now there's evidence that the idea of putting the concept into practice is gaining momentum:

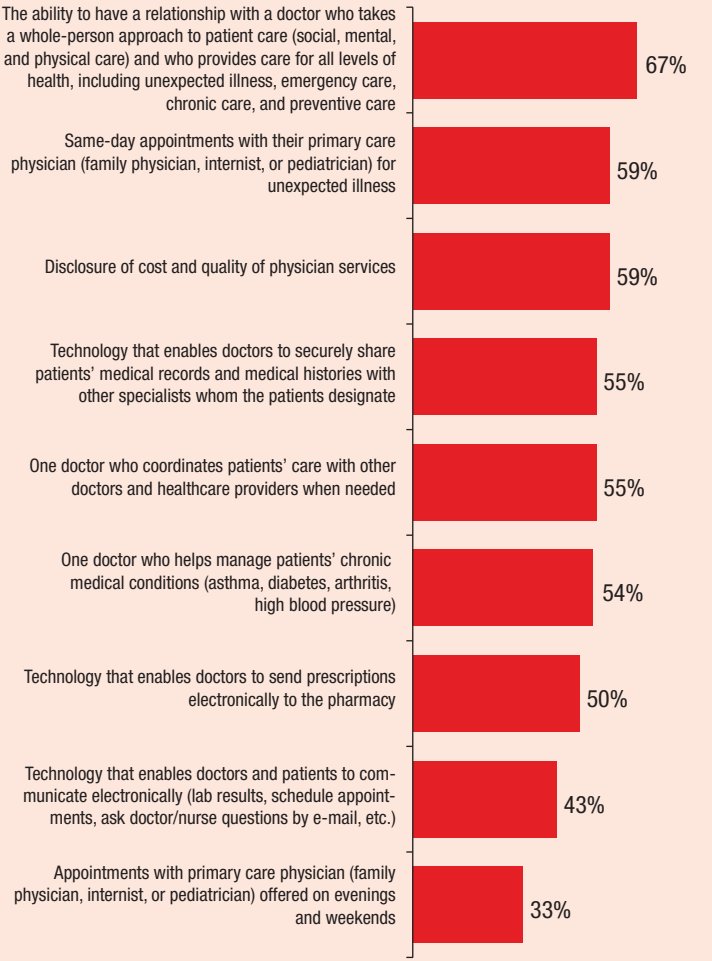
- The influential policy journal *Health Affairs* devoted more than 40 pages of its September/October 2008 issue to the medical home, and *The New England Journal of Medicine* carried 17 articles mentioning the medical home between 2007 and early 2009.
- Several dozen bills are pending in various state legislatures to study the medical home model or incorporate it into the public health or insurance systems.
- In October 2008, the AAP announced that it had received five-year funding for the National Center for Medical Home Implementation from the federal Maternal and Child Health Bureau.
- In January of this year, the Centers for Medicare and Medicaid Services started a three-year medical home demonstration project that could result in paying physicians who restructure their practices to provide services $10,000 to $25,000 per month. (See "Medicare Gets in the Game," p. 25.)
- The PCPPC, a provider-payer group, lists 22 medical home projects either planned or in progress in 17 states.

It's Not Gatekeeping

Primary care physicians with long memories may think a medical home sounds suspiciously like the "gatekeeper" concept

Survey : Evaluating Healthcare Elements
Extremely/Very Important

Question: When it comes to healthcare, how important are each of the following for you and/or your family members? When answering, please consider "family" to include a spouse/significant other, child/children, and/or adult relative(s) (parent, grandparent) you are responsible for making healthcare decisions for, even if they do not physically live with you. (Extremely important, very important, important, somewhat important, not at all important) (N=2,022)



Source: Reprinted with permission. "Executive Summary: Patient-Centered Medical Home Election Study," Patient-Centered Primary Care Collaborative, October 2008.

from the early days of managed care. At that time, primary care physicians were the "front line," keeping patients from getting expensive specialty care unless it was crucial. But Ms. Abrams says the medical home is different because it is voluntary for both physician and patient. Patients will be able to bypass their primary care physician and go directly to a specialist if they choose. Also, unlike the per-patient, or "capitation" payments that HMOs paid annually to primary care physicians, medical home reimbursement models try to confine any physician risk to factors that they can control. And finally, the medical home idea came from physicians, not payers.

"The goal of the medical home is not only to describe a better way of providing care, but to reinvigorate primary care," says Michael Barr, MD, vice president of practice advocacy and improvement for the ACP.

Researchers are already looking at the few practices that set out to be medical homes to evaluate their results. The Center for Home Improvement (CMHI) in Greenfield, N.H., for example, recently completed a study of 43 medical home practices in five states. While the specific results are still awaiting publication, these practices are the first to demonstrate tangible benefits, specifically fewer hospitalizations, emergency room (ER) visits, and other expensive acute interventions, says W. Carl Cooley, MD, CHMI's medical director.

A Primary Care Crisis

The medical home model of care is being sold not only as a boon to patients and a potential cost-cutting measure for the entire healthcare system, but also as an essential lifeline for a beleaguered profession.

ACP combined two alarming sets of statistics in an October 2008 white paper—the increasing U.S. population, especially those over 65 and with chronic illnesses, and the shrinking pool of primary care physicians. ACP concluded that the primary care profession is on its way to oblivion without drastic action (see *http://www.acponline.org/advocacy/where_we_stand/policy/primary_shortage.pdf*). For example, between 1997 and 2005, the number of U.S. medical graduates entering family medicine residencies dropped by half. By 2007, only 23 percent of third-year

MOXATAG is indicated for the treatment of tonsillitis and/or pharyngitis secondary to *Streptococcus pyogenes (S. pyogenes)* in adults and pediatric patients 12 years and older. MOXATAG should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. The full 10-day course of therapy should be completed for effective treatment. Patients taking MOXATAG should not chew or crush tablet.

Important Safety Information

Use caution in patients with known serious hypersensitivity to amoxicillin or to other drugs in the same class or patients who have demonstrated anaphylactic reactions to beta-lactams. Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients on penicillin therapy. If an allergic reaction occurs, MOXATAG should be discontinued and appropriate therapy instituted. *Clostridium difficile* Associated Diarrhea (CDAD) has been reported with nearly all antibacterial agents, including

Please see brief summary of Prescribing Information on next page.

References: 1. MOXATAG Prescribing Information. MiddleBrook Pharmaceuticals, Inc. 2008. **2.** Kardas P. Patient compliance with antibiotic treatment for respiratory tract infections. *J Antimicrob Chemother.* 2002;49(6):897-903. **3.** Sclar DA, Tartaglione TA, Fine MJ. Overview of issues related to medical compliance with implications for the outpatient management of infectious diseases. *Infect Agents Dis.* 1994;3(5):266-273.

New for the treatment of tonsillitis and/or pharyngitis secondary to *Streptococcus pyogenes*. . .

Once-Daily Amoxicillin Is Formed

Introducing MOXATAG™ **— Refining the delivery of amoxicillin therapy with innovative proprietary technology**

- Extended-release tablets efficiently deliver amoxicillin using a once-daily dose of 775 mg for 10 days[1]
- Proven efficacy for the treatment of tonsillitis/pharyngitis secondary to *S. pyogenes*[1]
- Convenient, once-daily dosing potentially leading to improved compliance[2,3]
- Favorable safety profile with observed minimal GI upset[1]

atag™

amoxicillin, and may range in severity from mild diarrhea to fatal colitis. If CDAD is suspected or confirmed, MOXATAG should be discontinued and appropriate therapy instituted. The possibility of superinfections with mycotic or bacterial pathogens should be kept in mind during therapy. If superinfections occur, MOXATAG should be discontinued and appropriate therapy instituted. The most common drug-related adverse reactions (incidence >1.0 %) are vulvovaginal mycotic infection, diarrhea, nausea, vomiting and headache.

once-daily

moxatag™

(amoxicillin extended-release tablets)

For more information, visit moxatag.com or call 1-877-MYMOXATAG

moxatag™

(amoxicillin extended-release tablets)

775 mg

The following is a brief summary only; see full Prescribing Information for complete product information.

RX ONLY

INDICATIONS AND USAGE

MOXATAG is a once-daily amoxicillin product indicated for the treatment of tonsillitis and/or pharyngitis secondary to *Streptococcus pyogenes (S. pyogenes)*, more commonly referred to as 'strep throat,' in adults and pediatric patients 12 years or older.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of MOXATAG and other antibacterial drugs, MOXATAG should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

DOSAGE AND ADMINISTRATION

The recommended dose of MOXATAG is 775 mg once daily taken within 1 hour of finishing a meal for 10 days. MOXATAG should be taken approximately the same time every day. The full 10-day course of therapy should be completed for effective treatment of tonsillitis and/or pharyngitis secondary to *S. pyogenes*.

Do not chew or crush tablet.

CONTRAINDICATIONS

MOXATAG is contraindicated in patients with known serious hypersensitivity to amoxicillin or to other drugs in the same class or patients who have demonstrated anaphylactic reactions to beta-lactams.

WARNINGS AND PRECAUTIONS

Anaphylaxis and Hypersensitivity Reactions

Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients on penicillin therapy. Although anaphylaxis is more frequent following parenteral therapy, it has occurred in patients on oral penicillins. 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 reports of individuals with a history of penicillin hypersensitivity who have experienced severe reactions when treated with cephalosporins. Before initiating therapy with MOXATAG, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, or other allergens. If an allergic reaction occurs, MOXATAG should be discontinued and appropriate therapy instituted.

***Clostridium difficile* Associated Diarrhea (CDAD)**

Clostridium difficile Associated Diarrhea (CDAD) has been reported with nearly all antibacterial agents, including amoxicillin, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*.

CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued.

Superinfections

The possibility of superinfections with mycotic or bacterial pathogens should be kept in mind during therapy. If superinfections occur, amoxicillin should be discontinued and appropriate therapy instituted.

Mononucleosis Rash

A high percentage of patients with mononucleosis who receive ampicillin develop an erythematous skin rash. Thus, ampicillin-class antibiotics should not be administered to patients with mononucleosis.

Development of Drug-Resistant Bacteria

Prescribing amoxicillin in the absence of proven or strongly suspected bacterial infection or treating prophylactically is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

False-Positive Urinary Glucose Tests

High urine concentrations of ampicillin may result in false-positive reactions when testing for the presence of glucose in urine using Clinitest®, Benedict's Solution or Fehling's Solution. Since this effect may also occur with amoxicillin, it is recommended that glucose tests based on enzymatic glucose oxidase reactions (such as Clinistix®) be used.

ADVERSE REACTIONS

In a controlled Phase 3 trial, 302 adult and pediatric patients (≥12 years) were treated with MOXATAG 775 mg once-daily for 10 days. The most frequently reported adverse reactions (>1%) which were suspected or probably drug-related are vaginal yeast infection (2.0%), diarrhea (1.7%), nausea (1.3%) and headache (1.0%).

DRUG INTERACTIONS

Probenecid

Probenecid decreases the renal tubular secretion of amoxicillin. Concurrent use of MOXATAG and probenecid may result in increased and prolonged blood levels of amoxicillin.

Other Antibiotics

Chloramphenicol, macrolides, sulfonamides, and tetracyclines may interfere with the bacterial effects of penicillin. This has been demonstrated *in vitro*; however, the clinical significance of this interaction is not well documented.

Oral Contraceptives

As with other antibiotics, amoxicillin may affect the gut flora, leading to lower estrogen reabsorption and potentially resulting in reduced efficacy of combined oral estrogen/progesterone contraceptives.

USE IN SPECIFIC POPULATIONS

Pregnancy: Teratogenic Effects. Pregnancy Category B.

Reproduction studies have been performed in mice and rats at doses up to 2000 mg/kg (12.5 and 25 times the human dose in mg/m^2) and have revealed no evidence of impaired fertility or harm to the fetus due to amoxicillin. 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.

Labor and Delivery

It is not known whether use of amoxicillin in humans during labor or delivery has immediate or delayed adverse effects on the fetus, prolongs the duration of labor, or increases the likelihood that forceps delivery or other obstetrical intervention or resuscitation of the newborn will be necessary.

Nursing Mothers

Penicillins have been shown to be excreted in human milk. Amoxicillin use by nursing mothers may lead to sensitization of infants. Caution should be exercised when amoxicillin is administered to a nursing woman.

Pediatric Use

The safety and effectiveness of MOXATAG in pediatric patients 12 years of age and older have been established based on results of a clinical trial that included adults and pediatric patients (12 years or older). The safety and effectiveness of MOXATAG in pediatric patients younger than 12 years has not been established.

Geriatric Use

This drug is known to be substantially excreted by the kidney, and the risk of adverse reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Renal Impairment

MOXATAG has not been studied in patients with renal impairment; however, a reduction of amoxicillin dose is generally recommended for patients with severe renal impairment. Therefore, MOXATAG is not recommended for use in patients with severe renal impairment (CrCl <30 mL/min) or patients on hemodialysis.

OVERDOSAGE

In case of overdose, discontinue medication, treat symptomatically, and institute supportive measures as required. If the overdose is very recent and there is no contraindication, an attempt at emesis or other means of removal of drug from the stomach may be performed.

Interstitial nephritis resulting in oliguric renal failure has been reported in a small number of patients after overdosage with amoxicillin.

Crystalluria, in some cases leading to renal failure, has also been reported after amoxicillin overdosage in adult and pediatric patients.

Renal impairment appears to be reversible with cessation of drug administration. High blood levels may occur more readily in patients with impaired renal function because of decreased renal clearance of amoxicillin.

For additional information about overdose treatment, call a poison control center (1-800-222-1222).

HOW SUPPLIED/STORAGE AND HANDLING

MOXATAG tablets for oral administration are provided as blue film-coated, oval-shaped tablets that contain 775 mg of amoxicillin. The tablets are printed with "MB-111" on one side in black edible ink. MOXATAG is packaged in bottles as follows:

Presentation	NDC Code
Bottles of 30	11042-142-03

Storage

Store at 25º C (77º F); excursions permitted to 15–30º C (59–86º F) [See USP Controlled Room Temperature.]

MiddleBrook PHARMACEUTICALS®
Germantown, Maryland 20876 USA

U.S. Patents 6,544,555; 6,669,948; 6,723,341

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internal medicine residents planned to practice general internal medicine compared with 54 percent in 1998. A 2008 survey in the *Journal of the American Medical Association* showed that while almost one quarter of students were planning to pursue a career in internal medicine, only two percent were interested in general internal medicine. Finally, many primary care physicians are retiring early—11 percent in the next three years, according to the Physicians' Foundation, and another 20 percent plan to cut back on the number of patients they see.

If primary care doesn't become more appealing to physicians, and quickly, it could leave the healthcare system to deal with most patients through specialists and ERs. That's why the medical home, in transforming the way primary care is delivered, also needs to transform the way it's compensated, dramatically in favor of primary care physicians.

The AAFP came up with a list of capabilities that practices must have in order to be considered a medical home. They include a team approach to care, registries for chronic illness to help track patients as groups, advanced information technology for electronic medical records (EMRs), e-prescribing, and patient communication and education.

"Even if we could click a switch and change the payment system, most practices don't have those things in place," says Bruce Bagley, MD, medical director for quality improvement at the AAFP. "We need to make them aware that they have to have these capabilities to be up in order to speed once the payment system is ready."

First Steps

Several major initiatives are helping primary care move toward the medical home model of care.

TransforMED

The AAFP's effort is TransforMED, an affiliate that helps practices make the changes they need to become a medical home (see *http://www.transformed.com/whoweare.cfm*.). TransforMED didn't originally have the words "medical home" in its core mission. But the strategies that it was advocating turned out to dovetail beautifully with the medical home philosophy, and

over the past two years TransforMED has come to embrace the terminology as well.

TransforMED worked with 36 practices in a two-year national demonstration project, for which a final report is due late this year or early next year. It is now offering its services to any primary care practice through either its consultants or do-it-yourself tools available on its Website. TransforMED is also beginning to work with family practice residency programs to teach the new model.

The Patient-Centered Primary Care Collaborative

In 2006, the PCPCC (*http://www.pcpcc.net*), a provider-payer-employer organization with more than 300 institutional members, was formed. Paul Grundy, MD, who may well be remembered as the father, or at least the godfather, of the patient-centered medical home, was at the helm. (His official title now is chairman.) He asked the four main primary care specialty societies—AAP, AAFP, ACP, and the AOA—to develop a set of principles for the medical home. After months behind closed doors, they came up with the joint principles on page 15. In November 2008, the American Medical Association (AMA) signed on; 17 other medical groups, including the American Academy of Cardiology, have added their endorsement, as have seven health benefits companies. The collaborative's goal is to get payers and providers on the same page.

The medical home may not be warmly embraced by either hospitals or specialists. If the incomes of other providers continue to depend on volume, the ability of primary care physicians to change the system single-handedly is going to be limited.

Dr. Grundy estimates that it takes two or three years for a practice to transform itself. "This is probably a 10- or 15-year journey," he says. "It takes a long time for practices to change and for residency to change. It's a big change from episodic care to robust, data-driven prevention, but there's no other answer."

Medicare Gets in the Game

When it comes to changing the face of U.S. medical care, no single agent is more influential than the Centers for Medicare and Medicaid Services (CMS), and 2009 is the year in which CMS is beginning to test the medical home concept.

Now CMS is recruiting 400 practices in eight states, aiming for a total of 2,000 physicians, to receive a more-than-token extra payment for revamping their practices to provide medical home services. The payments will range from $40.40 to $100.35 per patient per month, depending on the level of medical home services provided by the practice and on how much care is needed. CMS has made an electronic medical record a prerequisite for participation and will have two possible tiers of "medical homeness" based on criteria the NCQA has adapted from its medical home recognition program (see Chapter 2).

CMS estimates that participating physicians will care for an average of 250 Medicare patients each, which puts the potential medical home payments at $10,000 to $25,000 per month, assuming the physicians can convince all of their Medicare patients to participate. Since the medical home concept puts some onus on patients, especially those who are chronically ill, to participate in their treatment, patients have to agree to be part of the trial. Payments would begin January 2010 and continue through December 2012. The practices would also continue to receive their usual fees for any covered Medicare services.

The American College of Physicians Website keeps track of what's happening with the Medicare demonstration: *http://www.acponline.org/running_practice/pcmh/demonstrations/cms_ demo.htm.*

Medicare's Medical Home Management Fee

Payments Per Member Per Month

Medical Home Tier	Patients with HCC* Score <1.6	Patients with HCC Score ≥1.6	Blended Rate
1	$27.12	$80.25	$40.40
2	35.48	100.35	51.70

**HCC: Hierarchical condition categories.*

- HCC score indicates disease burden and predicted future costs to Medicare.
- Nationwide, 25% of beneficiaries have HCC ≥1.6, and are expected to have Medicare costs that are at least 60% higher than average.

*Source: "*Medicare Medical Home Demonstration Overview*," Centers for Medicare & Medicaid, Oct. 28, 2008. Information is subject to change.*

All Aboard?

Getting payers, employers, and primary care providers to cooperate is a promising first step, but successful medical homes aren't built in the middle of nowhere. Elliott S. Fisher, MD, director of the Center for Health Policy Research at the Dartmouth Institute for Health Policy and Clinical Practice in Lebanon, N.H., says there's no point in instituting the medical home without a "medical neighborhood" to go with it. Writing in the September 18, 2008, issue of *The New England Journal of Medicine*, he called for cooperation from other providers, effective payment reform, and acceptance of the idea by consumers, who evidently think of nursing homes when they hear the term "medical home."

Dr. Fisher points out that Medicare and other payers think of the medical home as a zero-sum game: Increased payments to primary care doctors will be offset (at the very least) by reduced payments for unnecessary ER visits, inpatient admissions, and specialty visits. As a result, the medical home may not be warmly embraced by either hospitals or specialists. If the incomes of other providers continue to depend on volume, the ability of primary care physicians to change the system single-handedly is going to be limited.

"I think the model offers great promise, but there will be challenges … in getting everyone to play ball unless there are incentives for all," Dr. Fisher says.

Dr. Chagnon, whose multiply afflicted patient—described at the beginning of this chapter—exemplified problems with the system today, would certainly champion that thought. Now that his practice is participating in the Albany-area medical home pilot program (described in Chapter 4), he sees a bright future for primary care. "I love being a family doctor, and I've had special relationships with my patients for 35 years; but I'm not doing as well at it now as I was 20 years ago," he says. "I'm very excited about the project and the concept."

Quiz: Is Your Practice a Medical Home?

You may think your practice is already a medical home, but is it really? Probably not entirely, says Melinda K. Abrams, assistant vice president at the Commonwealth Fund and director of its Patient-Centered Primary Care Program. "A lot of practices may have the relationships with their patients and offer them access, but they rarely do the care coordination piece or have the infrastructure needed to manage their panel," she says.

Take this quiz to see how your practice rates:

Yes	No	
☐	☐	**1.** Is your office staff organized into teams (for example, a physician, a nurse, and a physician's assistant)?
☐	☐	**2.** Does each patient have a relationship with a specific care team?
☐	☐	**3.** Can patients see a member of their team the day they call?
☐	☐	**4.** Is someone on the team responsible for seeing that its patients get all routine exams and tests, and for monitoring chronically ill patients by phone or e-mail?
☐	☐	**5.** Does your practice have electronic medical records?
☐	☐	**6.** Can you easily compile a list of patients who are due for a specific test?
☐	☐	**7.** Can your patients communicate with you easily in other ways besides an office visit (for example, via phone, text message, or e-mail)?
☐	☐	**8.** Is each team aware of (and, when necessary, in communication with) patients' other healthcare providers?
☐	☐	**9.** Do you offer group visits for patients who share common illnesses or conditions and need to learn the same self-care regimens?
☐	☐	**10.** Does your practice actively involve patients in making choices about their treatment?

If you answered yes to all these questions, you're in good shape to receive medical home "recognition," a National Committee for Quality Assurance designation (see Chapter 2 for more information). If you said yes to seven questions, you're well on your way. Fewer than five? You still have work to do.