Enhancing Practice Effectiveness

In medicine today, everyone is so busy that it’s difficult to justify the time and expense required to fully implement health information technology (HIT). But many practices that have made the switch have found that the result is worth the effort in terms of efficiency and quality of care.

Chapter in Brief:

▲ According to the Centers for Disease Control and Prevention (CDC), 12.4 percent of office-based physicians in the U.S. reported using “comprehensive” electronic medical records (EMRs), up from 9.3 percent a year earlier.

▲ Even if most doctors aren’t ready for HIT, the public is: a survey commissioned by the Blue Shield of California Foundation and conducted by the AARP found that 95 percent of respondents 65 and older wished their doctors had a device to check insurance coverage and medication history.

▲ A report from the Medical Group Management Association indicates that the most successful practices spend only slightly more on HIT than the typical practice. Many successful practices credit technology as a major factor in the quality of care and the efficiency of their operations.

▲ Technology has disadvantages, too: it can magnify and perpetuate errors by encouraging “cutting and pasting” instead of recording detailed notes.

▲ Healthcare reform—specifically HIT—tops the agenda no matter who moves into the White House in January 2009.
Important Safety Information

Patients being treated with BYSTOLIC should be advised against abrupt discontinuation of therapy. Severe exacerbation of angina and the occurrence of myocardial infarction and ventricular arrhythmias have been reported following the abrupt cessation of therapy with beta blockers. When discontinuation is planned, the dosage should be reduced gradually over a 1- to 2-week period and the patient carefully monitored.

BYSTOLIC is contraindicated in severe bradycardia, heart block greater than first degree, cardiogenic shock, decompensated cardiac failure, sick sinus syndrome (unless a permanent pacemaker is in place), severe hepatic impairment (Child-Pugh >B), and in patients who are hypersensitive to any component of this product.

BYSTOLIC should be used with caution in patients with peripheral vascular disease, thyrotoxicosis, in patients treated concomitantly with beta blockers and calcium channel blockers of the verapamil and diltiazem type (ECG and blood pressure should be monitored), severe renal impairment, and any degree of hepatic impairment or in patients undergoing major surgery. In patients who have compensated congestive heart failure, BYSTOLIC should be administered cautiously. If heart failure worsens, discontinuation of BYSTOLIC should be considered. Caution should also be used in diabetic patients as beta blockers may mask some of the manifestations of hypoglycemia, particularly tachycardia.

Use caution when BYSTOLIC is co-administered with CYP2D6 inhibitors (quinidine, propafenone, fluoxetine, paroxetine, etc). When BYSTOLIC is administered with fluoxetine, significant increases in d-nebivolol may be observed (ie, an 8-fold increase in AUC).

In general, patients with bronchospastic disease should not receive beta blockers.

BYSTOLIC should not be combined with other beta blockers.

The most common adverse events with BYSTOLIC versus placebo (approximately ≥1% and greater than placebo) were headache, fatigue, dizziness, diarrhea, nausea, insomnia, chest pain, bradycardia, dyspnea, rash, and peripheral edema.

Please see brief summary of Prescribing Information on adjacent page.


For the treatment of hypertension

BYSTOLIC.

Significant blood pressure reductions with a low incidence of side effects.
Bystolic (netivolol) tablets 2.5 mg, 5 mg, 10 mg and 20 mg

Brief Summary: For complete details please see full Prescribing Information for Bystolic.

INDICATIONS AND USAGE
Bystolic is indicated for the treatment of hypertension. Bystolic may be used alone or in combination with other antihypertensive agents.

CONTRAINDICATIONS
Bystolic is contraindicated in patients with severe bradycardia, heart block greater than first degree, cardiogenic shock, decompensated cardiac failure, sick sinus syndrome (unless a permanent pacemaker is in place), or severe hepatic impairment (Child-Pugh B), and in patients who are hypersensitive to any component of this product.

WARNINGS
Abrupt Cessation of Therapy
Patients with coronary artery disease treated with Bystolic should be advised against abrupt discontinuation of therapy. Severe exacerbation of angina and the occurrence of myocardial infarction and ventricular arrhythmias have been reported in patients with coronary artery disease following the abrupt discontinuation of therapy with β-blockers. Myocardial infarction and ventricular arrhythmias may occur with or without preceding exacerbation of the angina pectoris. Even patients without overt coronary artery disease should be cautioned against interruption or abrupt discontinuation of therapy. As with other β-blockers, when discontinuation of Bystolic is planned, patients should be carefully observed and advised to minimize physical activity. Bystolic should be tapered over 1 to 2 weeks when possible. If the angina worsens or acute coronary insufficiency develops, it is recommended that Bystolic be promptly re instituted, at least temporarily.

Cardiac Failure
Sympathetic stimulation is a vital component supporting circulatory function in the setting of congestive heart failure, and β-blockade may result in further depression of myocardial contractility and precipitate more severe failure. In patients who have compensated congestive heart failure, Bystolic should be administered cautiously. If heart failure worsens, discontinuation of Bystolic should be considered.

Angina and Acute Myocardial Infarction
Bystolic was not studied in patients with angina pectoris or who had a recent MI.

Bronchospastic Diseases
In general, patients with bronchospastic diseases should not receive β-blockers.

Anesthesia and Major Surgery
If Bystolic is to be continued perioperatively, patients should be closely monitored, because the added catecholamine-depleting drugs, such as reserpine or guanethidine, should be discontinued for several days before the gradual tapering of clonidine.

Dysynergia and Hypoglycemia
β-blockers may mask some of the manifestations of hypoglycemia, particularly tachycardia. Nonselective β-blockers may potentiate insulin-induced hypoglycemia and delay recovery of serum glucose levels. It is not known whether β-blockers may mask some of the manifestations of hyperglycemia, particularly tachycardia.

Diabetes and Hypoglycemia
β-blockers may precipitate or aggravate symptoms of arterial insufficiency in patients with peripheral vascular disease. Caution should be exercised in these patients.

Non-dihydropyridine Calcium Channel Blockers
Because of significant negative inotropic and chronotropic effects in patients treated with β-blockers and calcium channel blockers of the verapamil and diltiazem type, caution should be used in patients treated concomitantly with these agents and ECG and blood pressure should be monitored.

PRECAUTIONS
Use with CYP2D6 Inhibitors
Netivolol exposure increases with inhibition of CYP2D6 (see Drug Interactions). The dose of Bystolic may need to be reduced.

Impaired Renal Function
Bystolic should be used with caution in patients with severe renal impairment because of decreased renal clearance. Bystolic has not been studied in patients receiving dialysis.

Impaired Hepatic Function
Bystolic should be used with caution in patients with moderate hepatic impairment because of decreased metabolism. Since Bystolic has not been studied in patients with severe hepatic impairment, Bystolic is contraindicated in this population (see CLINICAL PHARMACOLOGY, Special Populations and DOSAGE AND ADMINISTRATION).

Risk of Anaphylactic Reactions
While taking β-blockers, patients with a history of severe anaphylactic reactions to a variety of allergens may be more reactive to repeated challenge either accidental, diagnostic, or therapeutic. Such patients may be unresponsive to the usual doses of epinephrine used to treat allergic reactions.

In patients with known or suspected pheochromocytoma, an β-blocker should be initiated prior to the use of any β-blocker.

Information for Patients
Patients should be advised to take Bystolic regularly and continuously, as directed. Bystolic can be taken with or without food. If a dose is missed, the patient should take the next scheduled dose only (without doubling it). Patients should not interrupt or discontinue Bystolic without consulting the physician.

Patients should know how they react to this medicine before they operate automobiles, use machinery, or engage in other tasks requiring alertness.

Patients should be advised to consult a physician if any difficulty in breathing occurs, or if they develop signs or symptoms of worsening heart failure such as weight gain or increasing shortness of breath, or excessive bradycardia.

Patients subject to spontaneous hypoglycemia, or diabetic patients receiving insulin or oral hypoglycemic agents, should be cautioned that β-blockers may mask some of the manifestations of hypoglycemia, particularly tachycardia.

Netivolol should be used with caution in these patients.

Drug Interactions
Bystolic should be used with care when myocardial depressants or inhibitors of AV conduction, such as certain calcium antagonists (particularly the phenylalkylamine [verapamil] and benzothiazepine [diltiazem] classes), or antiarrhythmic agents, such as disopyramide, are used concurrently. Both digoxin, glycosides and β-blockers slow atrioventricular conduction and decrease heart rate. Concomitant use can increase the risk of bradycardia.

Bystolic should not be combined with other β-blockers. Patients receiving catecholamine-depleting drugs, such as reserpine or guanethidine, should be closely monitored, because the added β-blocking action of Bystolic may produce excessive reduction of sympathetic activity. In patients who are receiving Bystolic and clonidine, Bystolic should be discontinued for several days before the gradual tapering of clonidine.

CYP2D6 Inhibitors:
Use caution when Bystolic is co-administered with CYP2D6 inhibitors (quinidine, propafenone, fluoxetine, paroxetine, etc.) (see CLINICAL PHARMACOLOGY, Drug Interactions).

Carcinogenesis, Mutagenesis, Impairment of Fertility
In a two-year study of nebivolol in mice, a statistically significant increase in the incidence of testicular Leydig cell hyperplasia and adrenomas was observed at 40 mg/kg/day (5 times the maximally recommended human dose of 40 mg on a mg/m² basis). Similar findings were not reported in mice administered doses equal to approximately 0.3 or 1.2 times the maximum recommended human dose. No evidence of a tumorigenic effect was observed in a 24-month study in Wistar rats receiving doses of nebivolol 2.5, 10 and 40 mg/kg/day (equivalent to 0.8, 2.4, and 10 times the maximally recommended human dose). Co-administration of dihydrotestosterone reduced blood LH levels and prevented the Leydig cell hyperplasia, consistent with an indirect LH-mediated effect of nebivolol in mice and not thought to be clinically relevant in man. A randomized, double-blind, placebo- and active-controlled, parallel-group study in healthy male volunteers was conducted to determine the effects of nebivolol on adrenal function, luteinizing hormone, and testosterone levels. This study demonstrated that 6 weeks of daily dosing with 10 mg of nebivolol had no significant effect on ACTH-stimulated mean serum cortisol AUC₀₋₁₂₀₆₀ min, serum LH, or serum total testosterone.

Effects on spermatogenesis were seen in male rats and mice at ≥40 mg/kg/day (10 and 5 times the MRHD, respectively). For rats the effects on spermatogenesis were not reversed and may have worsened during a four-week recovery period. The effects of nebivolol on sperm in mice, however, were partially reversible.

Mutagenesis:
Nebivolol was not genotoxic when tested in a battery of assays (Ames, in vitro mouse lymphoma TK⁺⁻, in vitro human peripheral lymphocyte chromosome aberration, in vivo Drosophila melanogaster sex-linked recessive lethal, and in vivo mouse bone marrow micronucleus tests).

Pregnancy:
Teratogenic Effects.

Pregnancy Category C:
Decreased pup body weights occurred at 1.25 and 2.5 mg/kg in rats, when exposed during the peri natal period (late gestation, parturition and lactation). At 5 mg/kg and higher doses (1.2 times the MRHD), prolonged gestation, dystocia and reduced maternal care were produced with corresponding increases in late fetal deaths and stillbirths and decreased birth weight, live litter size and pup survival. Insufficient numbers of pups survived at 5 mg/kg to evaluate the offspring for reproductive performance.
In studies in which pregnant rats were given nebivolol during organogenesis, reduced fetal body weights were observed at maternally toxic doses of 20 and 40 mg/kg/day (5 and 10 times the MRHD), and small reversible delays in sternal and thoracic ossification associated with the reduced fetal body weights and a small increase in resorption occurred at 40 mg/kg/day (10 times the MRHD).

No adverse effects on embryo-fetal viability, sex, weight or morphology were observed in studies in which nebivolol was given to pregnant rabbits at doses as high as 20 mg/kg/day (10 times the MRHD).

Labor and Delivery
Nebivolol caused prolonged gestation and dystocia at doses ≥5 mg/kg in rats (1.2 times the MRHD). These effects were associated with increased fetal deaths and stillborn pups, and decreased birth weight, live litter size and pup survival rates. events occurred only when nebivolol was given during the perinatal period (late gestation, parturition and lactation).

No studies of nebivolol were conducted in pregnant women. BYSTOLIC should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers
Studies in rats have shown that nebivolol or its metabolites cross the placental bar-
rier and are excreted in breast milk. It is not known whether this drug is excreted in human milk.

Because of the potential for β-blockers to produce serious adverse reactions in
nursing infants, especially bradycardia, BYSTOLIC is not recommended during
nursing.

Geriatric Use
Of the 2800 patients in the U.S.-sponsored placebo-controlled clinical hyper-
tension studies, 478 patients were 65 years of age or older. No overall differences in
efficacy or in the incidence of adverse events were observed between older and younger patients.

Pediatric Use
Safety and effectiveness in pediatric patients have not been established. Pediatric studies in ages newborn to 18 years old have not been conducted because of incomplete characterization of developmental toxicity and possible adverse effects on long-term fertility (see Carcinogenesis, Mutagenesis, and Impairment of Fertility).

ADVERSE REACTIONS
The data described below reflect worldwide clinical trial exposure to BYSTOLIC in 6545 patients, including 5008 patients treated for hypertension and the remaining 1507 subjects treated for other cardiovascular diseases. Doses ranged from 0.5 mg to 40 mg. Patients received BYSTOLIC for up to 24 months, with over 1000 patients treated for at least 6 months, and approximately 1300 patients for more than one year. In placebo-controlled clinical trials comparing BYSTOLIC with placebo, discontinuation of therapy due to adverse events was reported in 2.8% of patients treated with nebivolol and 2.2% of patients given placebo. The most common adverse events that led to discontinuation of BYSTOLIC were headache (0.4%), nausea (0.2%) and bradycardia (0.2%).

Adverse Reactions in Controlled Trials
Table 1 lists treatment-emergent signs and symptoms that were reported in three 12-week, placebo-controlled monotherapy trials involving 1597 hypertensive patients treated with either 5 mg, 10 mg or 20-40 mg of BYSTOLIC and 205 patients given placebo and for which the rate of occurrence was at least 1% for patients treated with nebivolol and greater than the rate for those treated with placebo in at least one dose group.

Table 1. Treatment-Emergent Adverse Events with an Incidence of ≥1% in BYSTOLIC-Treated Patients and at a Higher Frequency than Placebo-Treated Patients

<table>
<thead>
<tr>
<th>Event</th>
<th>Placebo (%)</th>
<th>Nebivolol 5 mg (%)</th>
<th>Nebivolol 10 mg (%)</th>
<th>Nebivolol 20-40 mg (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal pain</td>
<td>6 (5)</td>
<td>9 (6)</td>
<td>6 (7)</td>
<td>7 (6)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>2 (2)</td>
<td>2 (2)</td>
<td>2 (2)</td>
<td>2 (3)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>2 (2)</td>
<td>2 (2)</td>
<td>3 (4)</td>
<td>4 (3)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>2 (2)</td>
<td>2 (2)</td>
<td>2 (3)</td>
<td>3 (2)</td>
</tr>
<tr>
<td>Nausea</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>1 (2)</td>
<td>3 (2)</td>
</tr>
<tr>
<td>Insomnia</td>
<td>0 (0)</td>
<td>1 (1)</td>
<td>1 (1)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Chest pain</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>1 (1)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Bradycardia</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Dyspnea</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>1 (1)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Rash</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>1 (1)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Peripheral edema</td>
<td>0 (0)</td>
<td>1 (1)</td>
<td>1 (1)</td>
<td>1 (1)</td>
</tr>
</tbody>
</table>

Other Adverse Events Observed During Worldwide Clinical Trials

Listed below are other reported adverse events with an incidence of at least 1% in the more than 5300 patients treated with BYSTOLIC in controlled or open-label trials, whether or not attributed to treatment, except for those already appearing in Table 1. Terms generally refer to informative, minor symptoms, or events unlikely to be attributable to drug because they are common in the population. These adverse events were in most cases observed at a similar frequency in placebo-treated patients in the controlled studies.

Body as a Whole: Anemia.

Gastrointestinal System Disorders: Abdominal pain.

Metabolic and Nutritional Disorders: Hypercholesterolemia and hyperuricemia.

Nervous System Disorders: Parasthesia.

Laboratory
In controlled monotherapy trials, BYSTOLIC was associated with an increase in BUN, uric acid, triglycerides and a decrease in HDL cholesterol and platelet count.

Events Identified from Spontaneous Reports of BYSTOLIC Received Worldwide

The following adverse events have been identified from spontaneous reports of BYSTOLIC received worldwide and have not been listed elsewhere. These adverse events have been chosen for inclusion due to a combination of seriousness, frequency of reporting or potential causal connection to BYSTOLIC. Events common in the population have generally been omitted. Because these events were reported voluntarily from a population of uncertain size, it is not possible to estimate their frequency or establish a causal relationship to BYSTOLIC exposure:

- Abnormal hepatic function (including increased AST, ALT and bilirubin), acute pulmonary edema, acute renal failure, atroventricular block (both second- and third-degree), bronchospasm, erectile dysfunction, hypersensitivity (including urticaria, allergic vasculitis and rare reports of angioedema), myocardial infarction, priapism, psoriasis, Raynaud’s phenomenon, peripheral ischemia/claudication, somnolence, syncope, thrombocytopenia, various rashes and skin disorders, vertigo, and vomiting.

OVERDOSAGE

In clinical trials and worldwide postmarketing experience there were reports of BYSTOLIC overdose. The most common signs and symptoms associated with BYSTOLIC overdose are bradycardia and hypotension. Other important adverse events reported with BYSTOLIC overdose include cardiac failure, dizziness, hyperglycemia, fatigue and vomiting. Other adverse events associated with β-blocker overdose include bronchospasm and heart block.

The largest known ingestion of BYSTOLIC worldwide involved a patient who ingested up to 500 mg of BYSTOLIC along with several 100 mg tablets of acetylsalicylic acid in a suicide attempt. The patient experienced hypotension, pallor, depressed level of consciousness, hypokinesia, hypotension, sinus bradycardia, hypoglycemia, hypokalemia, respiratory failure and vomiting. The patient recovered.

Due to extensive drug binding to plasma proteins, hemodialysis is not expected to enhance nebivolol clearance.

If overdose occurs, BYSTOLIC should be stopped and general supportive and specific symptomatic treatment should be provided. Based on expected pharmacologic actions and recommendations for other β-blockers, the following general measures should be considered when clinically warranted:

- Bradycardia: Administer IV atropine. If the response is inadequate, isoproterenol or another agent with positive inotropic properties may be given cautiously.
- Under some circumstances, transthoracic or transvenous pacemaker placement may be necessary.

Hypotension: Administer IV fluids and vaspressors. Intravenous glucagon may be useful.

Heart Block (second or third degree): Patients should be carefully monitored and treated with isoproterenol infusion. Under some circumstances, transthoracic or transvenous pacemaker placement may be necessary.

Congestive Heart Failure: Initiate therapy with digitalis glycoside and diuretics.

In certain cases, consideration should be given to the use of inotropic and vasodilating agents.

Bronchospasm: Administer bronchodilator therapy such as a short-acting inhaled β2-agonist and/or aminophylline.

Hypoglycemia: Administer IV glucose. Repeated doses of IV glucose or possibly glucagon may be required.

In the event of intoxication where there are symptoms of shock, treatment must be continued for a sufficiently long period consistent with the 12-19 hour effective half-life of BYSTOLIC. Supportive measures should continue until clinical stability is achieved.

Call the National Poison Control Center (800-222-1222) for the most current information on β-blocker overdose treatment.
According to the Centers for Disease Control and Prevention (CDC), 29.2 percent of office-based physicians in the U.S. reported using some form of EMR system in 2006. Although that represents a measurable jump from the 23.9 percent who claimed to use EMRs in 2005, usage of “comprehensive” EMRs was only at 12.4 percent—compared with 9.3 percent a year earlier—the CDC reports. This means that only

**“EMR” vs “EHR”**

Confused about these two terms? You’re hardly alone.

In the last couple of years, “electronic health record (EHR)” has become the preferred terminology for clinical records kept in computerized formats, largely because that is what the federal government and the Certification Commission for Healthcare Information Technology (CCHIT) have been using. But just as many people have made “electronic medical record (EMR)” synonymous with EHR.

There are some important distinctions, however.

In general, 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.

The CCHIT certification program, described in more detail in Chapter 2, breaks the EHR down into ambulatory, inpatient, and network components for the purpose of testing individual products for meeting standards for interoperability.

Both EMR and EHR have supplanted an earlier term, “computerized patient record (CPR)”, though the latter sometimes refers to a computerized representation of a paper chart. EMRs and EHRs generally contain real data that can be manipulated and analyzed, not just scanned images of paper forms.

Growing in cachet—if not significant public acceptance of the technology—is the personal health record (PHR), a patient-controlled component of a full EHR.

And on the management side of healthcare, applications may be referred to as practice management (PM) systems, physician practice management (PPM) software, or physician office management information systems (POMIS).
one in eight physicians nationwide who see patients in an office setting were using systems with computerized laboratory and prescription ordering, electronic imaging, or lab reporting, and were writing their clinical notes electronically.

Healthcare clearly is nowhere near as “wired” as the rest of people’s lives. And that may be a key reason for the 44,000 to 98,000 preventable deaths that the Institute of Medicine estimates occur each year in U.S. hospitals. “When patients see multiple providers in different settings, none of whom have access to complete information, it is easier for something to go wrong than when care is better coordinated,” the IOM states in the Executive Summary of the landmark report, “To Err is Human,” released in 1999. “At the same time, the provision of care to patients by a collection of loosely affiliated organizations and providers makes it difficult to implement improved clinical information systems capable of providing timely access to complete patient information. Unsafe care is one of the prices we pay for not having organized systems of care with clear lines of accountability.”

A growing number of doctors are realizing that technology can help.

The public clearly wants it. In a survey of seniors and caregivers called “Healthy @ Home,” commissioned by the Blue Shield of California Foundation and released in March 2008, the AARP found that seniors have an interest in health information technology. Ninety-five percent of respondents 65 and older wished their doctors had a device to check insurance coverage of specific drugs before writing a prescription and to check their medication history. Similarly, 92 percent would like their physicians to transmit prescriptions electronically to the pharmacy of their choice.

Three-fourths of the 65-plus survey pool would be willing to have a cardiologist diagnose or monitor a heart condition based on information transmitted electronically from home or a primary care doctor to the specialist. And 84 percent of Medicare-eligible Americans would search for health information on the Internet—nearly as many as were even aware that they could use a computer to find health information.

The problem, of course, is that healthcare information and
Benefits From Automation

For many who have made the transition and automated their practices, the improvement has been dramatic. In fact, it has rescued many a practice from near-insolvency.

“The practice was struggling enormously when I came on board in 2000,” says Victoria Waltemath, office manager of ABCD Pediatrics in San Antonio, Tex. That was around the time the founding physician left. “Fortunately, the two docs who took over the practice have a lot of business savvy.” In about 2002, the practice began a yearlong search for an EMR system, finally choosing EncounterPRO EMR, a product of EncounterPRO Healthcare Resources, an Atlanta company then known as JMJ Technologies. The practice management system is MARS Medical Systems’ NetPractice, now owned by Noteworthy Medical Systems, Cleveland, Oh. The decision set the stage for a turnaround at the practice.

ABCD today has seven full-time physicians, one who practices about 75 percent of the time, and two pediatric nurse practitioners. This year the practice was cited by the Medical Group Management Association (MGMA) as a success story in profitability and cost management, and an EMR system has facilitated much of the improvement.

“The key where the EMR has helped the most is that every one of us who needs access to the information has it at our fingertips whenever we need it,” according to Ms. Waltemath. “It also makes us look more professional because we don’t have stacks of paper lying around.” Perhaps as important for this pediatric practice, the less time staff members spend chasing down information, the more they can devote to face-to-face interaction with patients. It also helps them squeeze in last-minute appointments— something parents really appreciate. The EMR system’s in-office communication helps as well. The office is quieter and runs more smoothly—staff members know what to do, and they’re doing it instead of shouting to each other.

The EMR and practice management systems are tightly integrated, so staff don’t have to double-enter patient demographic knowledge remain scattered—in paper files, in countless journals and texts, and in doctors’ heads.
data, insurance information, diagnoses, or billing codes. “We also do a mini-audit on every claim before it goes out, just so we’re sure we haven’t forgotten anything,” Ms. Waldemath says. The “audit” consists of simply comparing the clinical documentation with the superbill.

The MGMA report that recognized ABCD Pediatrics indicates that the most successful group practices spend slightly more on information technology than the typical practice, which, in general, enables them to perform more revenue-producing procedures per physician and significantly reduces accounts-receivable cycles. Still, the sums are not all that great—“better-performing” multispecialty practices devote 1.73 percent of their medical revenue to IT, compared with a median of 1.49 percent, and the difference is less pronounced in pediatrics—suggesting that IT is not the single distinguishing characteristic of top performers. It is only a tool, not a panacea.

“The story here isn’t about technology, it’s about change,” Health and Human Services (HHS) Secretary Michael O. Leavitt said at February’s annual Healthcare Information and Management Systems Society (HIMSS) conference. “Technology is a key enabler of change.”

Change is difficult, especially after years of practice.

“Physicians are probably the most resistant-to-change there is,” says Allen Wenner, MD, a part-time practitioner at Twelve Mile Creek Family Medicine who also serves as vice president of clinical applications design for Primetime Medical Software in nearby Columbia, S.C. At a recent medical meeting, Dr. Wenner described how he has integrated technology into his practice. One of the physicians in the audience called his methods “impersonal and appalling,” Dr. Wenner recalls.

“My response was, ‘Let me understand what you are doing. You can’t look up information at the bedside. In other words, in your exam room, you can’t do research on the Internet to figure out a question you don’t know. You really don’t have information at your fingertips to determine the outcomes of studies or scientific information regarding that patient,’ which we all know can’t be kept in any physician’s head. It’s humanly impossible.”

Nor did the other physician have an EMR system, so Dr. Wenner believes there was a chance she was missing pertinent infor-
mation at the point of care. For example, without technology it’s difficult to follow the IOM’s recommendation to check drug interactions before prescribing. “Now help me understand why what you’re doing is better,” Dr. Wenner said to his critic.

Change on the Way

Many physicians are counting on retiring before being forced to change, but the revolution may happen sooner. “If you are not coming on board with this, you will be left behind,” says Karen M. Bell, MD, director of health information technology adoption in the HHS Office of the National Coordinator for Health Information Technology.

When Secretary Leavitt spoke in February, he urged the healthcare community to act on their own volition before the government mandates technology solutions. There will be a new administration next year, and thus new HHS leadership; but support for HIT seems to be bipartisan, particularly in the area of electronic prescribing.

Already, the Centers for Medicare and Medicaid Services (CMS) has set rules for e-prescribing under Medicare Part D rules that take effect April 1, 2009, to standardize communication between prescriber, health plan, and pharmacy for formulary and benefits information, medication history, and notification of fill status. CMS will also require providers, dispensers, and benefit sponsors to use the National Provider Identifier in all electronic Medicare Part D transactions. For CMS purposes, e-prescribing systems must have true electronic links between prescriber and pharmacy; faxes do not qualify.

In June, CMS and HHS officials announced that they had chosen 12 communities nationwide to participate in a demonstration program that will provide financial incentives to help small and midsize primary care practices adopt EMRs and use the systems to measure physician performance. If, as planned, 100 practices in each community participate, the five-year effort could improve the quality of care for as many as 3.6 million patients, according to HHS.

Still, skeptics of this technology and of these programs remain. “We’ve seen a lot of activity, but we haven’t seen a lot of progress,” laments West Chester, Pa., healthcare information
In 2003, the IOM identified eight “core functions” of an EHR:

**Health information and data.** According to the IOM, having timely access to key, patient-specific information such as diagnoses, allergies, laboratory results, and medications would improve the ability of practitioners to make informed, accurate clinical decisions.

**Results management.** Ready access to new and previous test results by all providers participating in the care of a patient, regardless of the setting, would increase patient safety and the effectiveness of care.

**Order management.** The ability to enter and store orders for prescriptions, tests, and other services in a computer-based system should enhance legibility, reduce duplication, and improve the speed and accuracy of order execution.

**Decision support.** Computerized clinical decision support in the form of electronic reminders, prompts, and alerts would help improve compliance with best practices, ensure regular screenings and other preventive care, identify possible drug interactions, and facilitate proper diagnoses and treatments.

**Electronic communication and connectivity.** Efficient, secure, and readily accessible communication among providers and patients would aid the continuity of care, improve the timeliness of diagnoses and treatments, and reduce adverse events.

**Patient support.** Tools that give patients access to their health records, provide interactive patient education, and help individuals monitor and test their conditions at home can improve control and management of chronic conditions.

**Administrative processes.** Computerized administrative tools, such as scheduling systems, would greatly improve the efficiency of healthcare facilities and allow provider organizations to deliver more timely service to patients.

**Reporting.** Electronic data storage following uniform data standards will enable healthcare organizations to respond more quickly to federal, state, and private reporting requirements, including those that support patient safety and disease surveillance.

Several executive orders since 2004 have encouraged the fed-
eral government to promote HIT, interoperability, and transparency of health information in its own activities and purchasing decisions. But numerous pieces of legislation to fund additional HIT measures have stalled in Congress each year.

**Cost-Benefit Ratio**

EMRs and EHRs are not infallible. They can magnify and perpetuate errors by encouraging doctors to cut and paste information, as two Harvard Medical School physicians documented in an April 17 article in the *New England Journal of Medicine*.

Deborah C. Peel, MD, founder and chairman of an Austin, Tex.-based organization known as the Patient Privacy Rights Foundation, is no fan of electronic prescribing or EMRs in their current state. She cites security shortcomings of the technology, the fact that so many IT vendors sell clinical information to data-mining firms, and what she believes are fundamental flaws in the federal privacy rules set under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Dr. Peel, a psychiatrist, says, “We absolutely oppose this kind of mandate unless it’s coupled with ending the rampant practice of the theft and sale of America’s prescription records. All of these systems are wired for data mining, and they in fact do data mine. And there’s no way that any Americans think they’ve given permission for that behavior, the use and the sale of that information.”

Dr. Peel’s criticism of EMRs is apparently shared by a substantial chunk of the public. Last year, about half of the 2,153 U.S. adults surveyed in a *Wall Street Journal* Online-Harris Interactive poll expressed concern that EMR use makes it more difficult to protect patient privacy, though this number has declined from 61 percent in a 2006 poll. Still, 60 percent said the benefits of EMRs outweigh the privacy risks.

Furthermore, only 27 percent of those whose medical records are kept on paper were “very confident” that their doctors had an accurate and complete idea of their medical history, while half of those with EMRs expressed the highest confidence.

EMR supporters within the healthcare industry like to tout the security of having an electronic audit trail, as HIPAA requires. Palisades Medical Center in North Bergen, N.J., suspended more
than 25 doctors, nurses, and other workers last year for allegedly
taking unauthorized peeks at the medical record of actor George
Clooney, who had been treated at the hospital following a motor-
cycle accident.

“In a paper world, you never know who’s looked at it,” says
Dr. Sarah Corley, chief medical officer, of ambulatory EMR ven-

The IOM has been calling for computerization of health infor-
mation since 1991, and there are myriad reasons why paper still
prevails and healthcare knowledge remains so disjointed. Some
reasons given include these: Technology might increase liability
risk. Nothing is standardized. Technology slows doctors down.
Electronic information is too vulnerable to hackers. Computers
disrupt the patient-physician dynamic.

And most of all, this technology is too expensive.

Indeed, HIT costs money, and healthcare providers dealing
with dwindling reimbursement do not have extra money or time
to invest in technology. Also, the reimbursement system cur-
cently rewards volume of service, not necessarily quality of serv-
ice, so providers may not see any financial reward for their
investment. Reducing duplicate testing because earlier records
can’t be found and preventing complications from errors save
money for payers, not necessarily providers. In other words,
providers foot the bill for clinical information technology, yet
payers reap the greatest financial benefit.

Still, a growing roster of other physicians have found ways to
work around all the barriers, disincentives, and potential pitfalls, sometimes by adding bits and pieces of technology, sometimes by overhauling their entire practices, and occasionally by starting from scratch.

From the individual physician’s point of view, “It’s very hard to compete with the efficiency in a paper-based chart,” says Dr. Charles Kilo, CEO of GreenField Health, a nine-physician group in Portland, Ore. It’s simple and quick to scribble a note in a paper chart or fire off a quick prescription on a pad. But in terms of managing the practice—not to mention the health sys-

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**Consumer Interest in Online Tools and Other Services Provided by Doctors**

<table>
<thead>
<tr>
<th>Service</th>
<th>Have used</th>
<th>Interested in using</th>
<th>Willing to pay extra</th>
</tr>
</thead>
<tbody>
<tr>
<td>Same-day appointment</td>
<td>35%</td>
<td>26%</td>
<td>83%</td>
</tr>
<tr>
<td>Online access to medical records and test results</td>
<td>6%</td>
<td>26%</td>
<td>78%</td>
</tr>
<tr>
<td>Online access to integrated medical record</td>
<td>3%</td>
<td>25%</td>
<td>76%</td>
</tr>
<tr>
<td>E-mail access to a doctor</td>
<td>9%</td>
<td>23%</td>
<td>76%</td>
</tr>
<tr>
<td>Online scheduling of appointments</td>
<td>10%</td>
<td>18%</td>
<td>72%</td>
</tr>
<tr>
<td>Website providing information about health conditions or treatments</td>
<td>12%</td>
<td>30%</td>
<td>69%</td>
</tr>
<tr>
<td>Website providing information about quality of doctor care</td>
<td>9%</td>
<td>11%</td>
<td>67%</td>
</tr>
<tr>
<td>Website providing information about prices of services</td>
<td>5%</td>
<td>9%</td>
<td>65%</td>
</tr>
<tr>
<td>Educational classes and meetings</td>
<td>9%</td>
<td>17%</td>
<td>56%</td>
</tr>
<tr>
<td>Assistance from a care coordinator</td>
<td>7%</td>
<td>10%</td>
<td>53%</td>
</tr>
<tr>
<td>Assistance from a patient billing representative</td>
<td>5%</td>
<td>8%</td>
<td>50%</td>
</tr>
</tbody>
</table>

*Source: 2008 Survey of Health Care Consumers, Deloitte Center for Health Solutions.*
ENHANCING PRACTICE EFFECTIVENESS

tem as a whole—technology makes the whole operation run more smoothly. He and his partners set out to design a medical practice that promotes preventive care, focuses on the needs of the patient, and—with the help of technology—maximizes efficiency throughout the process.

They began seeing patients in 2001, with an EHR and practice management system—a product now carrying the GE Healthcare Centricity brand name—in place since day one. “We have lots of really valuable add-on tools,” Dr. Kilo says. Among these extras are personal health records and a secure Web portal for communications between patients and physicians, since standard e-mail is not secure enough for HIPAA purposes.

Also successfully melding technology and process redesign is Village Health Partners in Plano, Tex. The practice, formerly known as Family Medical Specialists of Texas, won a 2007 Nicholas G. Davies Award for ambulatory care from HIMSS, honoring excellence in the use of IT. The three physicians from Family Medical Specialists combined with five other doctors to form Village Health Partners late last year.

Founding physician Dr. Christopher Crow knows that the out-of-pocket cost for care from a family practitioner in the North Dallas market will vary little from practice to practice, even for those patients with high-deductible insurance plans. “I can’t control the costs that much,” says Dr. Crow, who has an MBA from the University of Texas at Dallas. “But what I can control is access and convenience that no one else is [offering]. That’s our competitive advantage.”

To gain that advantage, he came up with processes to distinguish his own practice from everyone else’s.

He started by taking a look at common workflow in “the paper world,” such as triage call or prescription refill. Then he looked at what technology—specifically the software he purchased for the practice—could do to help improve that workflow, perhaps eliminating handoffs and streamlining use of time and resources. He recommends that other practices follow this process for “improving the error rate and customer service and the quality of the care delivered back to the patient.” Once the first cycle of improvement is completed, he says, “Then you do it over and over again, and you continue to try to streamline it and make the
TOPAMAX® Tablets and TOPAMAX® Sprinkle Capsules are indicated for adults for the prophylaxis of migraine headache. The usefulness of TOPAMAX® in the acute treatment of migraine headache has not been studied.

TOPAMAX® is contraindicated in patients with a history of hypersensitivity to any component of this product.

IMPORTANT SAFETY INFORMATION

TOPAMAX® has been associated with serious adverse events, including:

- Hyperchloremic, non-anion gap metabolic acidosis—lowering of bicarbonate levels in the blood. Measurement of baseline and periodic serum bicarbonate is recommended.
- Acute myopia and secondary angle-closure glaucoma—patients should be cautioned to seek medical attention if they experience blurred vision or ocular pain.
- Oligohidrosis and hyperthermia—decreased sweating and increased body temperature, especially in hot weather. The majority of reports have been in children.
- Cognitive/psychiatric side effects including cognitive dysfunction, psychiatric/behavioral disturbances including suicidal thoughts or behavior, and somnolence and fatigue.

Most common adverse events associated with TOPAMAX® 100 mg vs placebo were: paresthesia, 51% vs 6%; anorexia,* 15% vs 6%; fatigue, 15% vs 11%; nausea, 13% vs 8%; diarrhea, 11% vs 4%; weight decrease, 9% vs 1%; taste alteration, 8% vs 1%.

The possibility of decreased contraceptive efficacy and increased breakthrough bleeding should be
Prescribe TOPAMAX® first.

The #1 medication prescribed by neurologists for migraine prevention.¹

"TOPAMAX® has demonstrated significant efficacy in the largest well-controlled trials for migraine prevention."²

Jan Lewis Brandes, MD, MS
Assistant Clinical Professor Department of Neurology
Vanderbilt University School of Medicine
Nashville Neuroscience Group

TOPAMAX® has demonstrated significant efficacy in the largest well-controlled trials for migraine prevention.²

considered in patients taking combination oral contraceptive products with TOPAMAX®.

Patients should be instructed to maintain an adequate fluid intake in order to minimize the risk of renal stone formation.

*Anorexia is defined as loss of appetite.


Important
Avoid confusion with Toprol-XL® (metoprolol succinate) by spelling out TOPAMAX® (topiramate) on your prescription. Toprol-XL is a registered trademark of the AstraZeneca group of companies.

Please see brief summary of full Prescribing Information on following pages.

TOPAMAX® (topiramate) Tablets
www.TOPAMAX360.com

access2wellness™

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May 2008 02M07240ER1
Adverse Concomitant

Fatigue and somnolence were dose-related
The majority of cognitive-related

CONTRAINDICATIONS: TOPAMAX® is contraindicated in patients
with a history of hypersensitivity to any component of this product.

WARNINGS: Metabolic Acidosis: Hyperchloremic, non-anion gap, metabolic acidosis (i.e., decreased serum bicarbonate below
the normal reference range in the absence of chronic respiratory
alkalosis) is associated with topiramate treatment. This metabolic
acidosis is caused by renal bicarbonate loss due to the inhibitory
effect of topiramate on carbonic anhydrase. Such electrolyte imbalance has been observed with the use of topiramate in
placebo-controlled clinical trials and in the post-marketing period.
Generally, topiramate-induced metabolic acidosis occurs early in
treatment although cases can occur at any time during treatment.
Bicarbonate decrements are usually mild-moderate (average
decrease of 4 mEq/L at daily doses of 400 mg in adults and at
approximately 6 mg/kg/day in pediatric patients); rarely, patients
can experience severe decrements to values below 10 mEq/L.
Conditions or therapies that predispose to acidosis (such as renal
disease, severe respiratory disorders, status epilepticus,
diabetes, surgery, ketogenic diet, or drugs) may be additive to the
bicarbonate lowering effects of topiramate. Metabolic acidosis has been observed at doses as low as 50 mg/day. Serum
bicarbonate levels have not been systematically evaluated at
daily doses greater than 400 mg/day. The incidence of persistent
treatment-emergent decreases in serum bicarbonate in placebo-
controlled trials for adults for prophylaxis of migraine was 44% for
200 mg/day, 39% for 100 mg/day, 23% for 50 mg/day, and 7% for
placebo. The incidence of a markedly abnormally low serum bicarbonate (i.e., absolute value <17 mEq/L and >5 mEq/L
decrease from pretreatment) in these trials was 11% for 200 mg/day,
9% for 100 mg/day, 2% for 50 mg/day, and <1% for placebo. Some
manifestations of acute or chronic metabolic acidosis may
include hyperventilation, nonspecific symptoms such as fatigue
and anorexia, or more severe sequelae including cardiac
arrhythmias or stupor. Chronic, untreated metabolic acidosis may
increase the risk for nephrolithiasis or nephrocalcinosis, and may
also result in osteomalacia (referred to as rickets in pediatric
patients) and/or osteoporosis with an increased risk for fractures.
Chronic metabolic acidosis in pediatric patients may also reduce
growth rates. A reduction in growth rate may eventually decrease
the maximal height achieved. The effect of topiramate on growth
and bone-related sequelae has not been systematically
investigated. Measurement of baseline and periodic serum
bicarbonate during topiramate treatment is recommended. If
metabolic acidosis develops and persists, consideration should be
given to reducing the dose or discontinuing topiramate (using
dose tapering). If the decision is made to continue patients on
topiramate in the face of persistent acidosis, alkali treatment
should be considered. Acute Myopia and Secondary Angle
Closure Glaucoma: A syndrome consisting of acute myopia associated with secondary angle closure glaucoma has been
reported in patients receiving TOPAMAX®. Symptoms include
acute onset of decreased visual acuity and/or ocular pain.
Ophthalmologic findings can include myopia, anterior chamber
shallowing, ocular hyperemia (redness) and increased intraocular
pressure. Mydriasis may or may not be present. This syndrome
may be associated with suprachoroidal effusion resulting in anterior
displacement of the lens and iris, with secondary angle closure
glaucoma. Symptoms typically occur within 1 month of initiating
TOPAMAX® therapy. In contrast to primary narrow angle
glaucoma, which is rare under 40 years of age, secondary angle
closure glaucoma associated with topiramate has been reported in
pediatric patients as well as adults. The primary treatment to
reverse symptoms is discontinuation of TOPAMAX®, as rapidly as
possible, according to the judgment of the treating physician.
Other measures, in conjunction with discontinuation of
TOPAMAX®, may be helpful. Elevated intraocular pressure of any
etiology, if left untreated, can lead to serious sequelae including
permanent vision loss. Oligohidrosis and Hyperthermia:
Oligohidrosis (decreased sweating), infrequently resulting in
hospitalization, has been reported in association with TOPAMAX®,
use. Decreased sweating and an elevation in body temperature
above normal characterized these cases. Some of the cases
were reported after exposure to elevated environmental
temperatures. The majority of the reports have been in children.
Patients, especially pediatric patients, treated with TOPAMAX®
should be monitored closely for evidence of decreased sweating
and increased body temperature, especially in hot weather.
Caution should be used when TOPAMAX® is prescribed with
other drugs that predispose patients to heat-related disorders;
these drugs include, but are not limited to, other carbonic
anhydrase inhibitors and drugs with anticholinergic activity.
Cognitive/Neuropsychiatric Adverse Events: Adults: Adverse
events most often associated with the use of TOPAMAX® were
related to the central nervous system. In adults, the most frequent
of these can be classified into three general categories:
1) Cognitive-related dysfunction (e.g., confusion, psychomotor
slowing, difficulty with concentration/attention, difficulty with
memory, speech or language problems, particularly word-finding
difficulties); 2) Psychiatric/behavioral disturbances (e.g.,
depression or mood problems); and 3) Somnolence or fatigue.
Cognitive-Related Dysfunction: The majority of cognitive-related
adverse events were mild to moderate in severity, and they
frequently occurred in isolation. Rapid titration rate and higher
initial dose were associated with higher incidences of these
events. Many of these events contributed to withdrawal from
treatment (see ADVERSE REACTIONS, Table 1). In the 6-month
migraine prophylaxis controlled trials using a slower titration
regimen (25 mg/day weekly increments), the proportion of
patients who experienced one or more cognitive-related adverse
events was 19% for TOPAMAX® 50 mg/day, 22% for 100 mg/day,
28% for 200 mg/day, and 10% for placebo. These dose-related
adverse reactions typically began in the titration phase and often
persisted into the maintenance phase, but infrequently began in
the maintenance phase. Some patients experienced a recurrence
of one or more of these cognitive adverse events and this
recurrence was typically in the titration phase. A relatively small
proportion of topiramate-treated patients experienced more than
one concurrent cognitive adverse event. The most common
cognitive adverse events occurring together included difficulty
with memory along with difficulty with concentration/attention,
difficulty with memory along with language problems, and
difficulty with concentration/attention along with language
problems. Rarely, topiramate-treated patients experienced three
concurrent cognitive events. Psychiatric/Behavioral Disturbances:
Psychiatric/behavioral disturbances (depression or mood
problems) were dose-related for both the epilepsy and migraine
populations. In the double blind phases of clinical trials with
topiramate in approved and investigational indications, suicide
attempts occurred at a rate of 3/1000 patient years (13 events/
3999 patient years) on topiramate versus 0 (0 events/1430
patient years) on placebo. One completed suicide was reported
in a bipolar disorder trial in a patient on topiramate.
Somnia/Fatigue: Somnolence and fatigue were dose-related
and more common in the titration phase.
PRECAUTIONS: Hyperammonemia and Encephalopathy
Associated with Concomitant Valproic Acid Use: Concomitant
administration of topiramate and valproic acid has been
associated with hyperammonemia with or without
encephalopathy in patients who have tolerated either drug alone.
Clinical symptoms of hyperammonemic encephalopathy often
include acute alterations in level of consciousness and/or
Because of the potential of topiramate to cause CNS depression, as well as other cognitive and/or neuropsychiatric adverse events, topiramate should be used with extreme caution if used in combination with alcohol and other CNS depressants. Oral Contraceptives: In a pharmacokinetic interaction study in healthy volunteers with a concomitantly administered combination oral contraceptive product containing 1 mg norethindrone (NET) plus 35 mcg ethinyl estradiol (EE), TOPAMAX® given in the absence of other medications at doses of 50 to 200 mg/day was not associated with statistically significant changes in mean Cmax,ss and AUC0-12h of the active ketone metabolite. In another study, exposure to EE was statistically significantly decreased at doses of 200, 400, and 800 mg/day (18%, 21%, and 30%, respectively) when given as adjunctive therapy in patients taking valproic acid. In both studies, TOPAMAX® (50 mg/day to 800 mg/day) did not significantly affect exposure to NET. Although there was a dose dependent decrease in EE exposure for doses between 200-800 mg/day, there was no significant dose dependent change in EE exposure for doses of 50-200 mg/day. The clinical significance of the changes observed is not known. The possibility of decreased contraceptive efficacy and increased breakthrough bleeding should be considered in patients taking combination oral contraceptive products with TOPAMAX®. Patients taking estrogen containing contraceptives should be asked to report any change in their bleeding patterns. Contraceptive efficacy may be decreased with the addition of topiramate. In a drug-drug interaction study conducted in healthy volunteers evaluated the steady-state pharmacokinetics of HCTZ (25 mg q24h) and topiramate (96 mg q12h) when administered alone and concomitantly. The results of this study indicate that topiramate Cmax increased by 27% and AUC increased by 29% when HCTZ was added to topiramate. The clinical significance of this change is unknown. The addition of HCTZ to topiramate therapy may require an adjustment of the topiramate dose. The steady-state pharmacokinetics of HCTZ were not significantly influenced by the concomitant administration of topiramate. Clinical laboratory results indicated decreases in serum potassium after topiramate or HCTZ administration, which were greater when HCTZ and topiramate were administered in combination. Metformin: A drug-drug interaction study conducted in healthy volunteers evaluated the steady-state pharmacokinetics of metformin and topiramate in plasma when metformin was given alone and when metformin and topiramate were given simultaneously. The results of this study indicated that metformin mean Cmax increased by 27% and mean AUC12h increased by 18% and 25%, respectively, while mean CL/F decreased 20% when metformin was co-administered with topiramate. Topiramate did not affect metformin tmax. The clinical significance of the effect of topiramate on metformin pharmacokinetics is unclear. Oral plasma clearance of topiramate appears to be reduced when administered with metformin. The extent of change in the clearance is unknown. The clinical significance of the effect of metformin on topiramate pharmacokinetics is unclear. When TOPAMAX® is added or withdrawn in patients on metformin therapy, careful attention should be given to the routine monitoring for adequate control of their diabetic disease state. Pioglitazone: A drug-drug interaction study conducted in healthy volunteers evaluated the steady-state pharmacokinetics of topiramate and pioglitazone when administered alone and concomitantly. A 15% decrease in the AUC12h of pioglitazone with no alteration in Cmax,ss was observed. This finding was not statistically significant. In addition, a 13% and 16% decrease in Cmax,ss and AUC12h, respectively, of the active hydroxy-metabolite was noted as well as a 60% decrease in Cmax,ss and AUC12h of the active keto-metabolite. The clinical significance of these findings is not known. When TOPAMAX® is added to pioglitazone therapy or pioglitazone is added to TOPAMAX® therapy, careful attention should be given to the routine monitoring of patients for adequate control of their diabetic disease state. Lithium: Multiple dosing of topiramate 100 mg every 12 hrs decreased the AUC and Cmax of Lithium (300 mg every 8 hrs) by 20% (N=12, 6 M; 6 F). Haloperidol: The pharmacokinetics of a single dose of haloperidol (5 mg) were not affected following multiple dosing of topiramate (100 mg every 12 hr)
in 13 healthy adults (6 M, 7 F). Amitriptyline: There was a 12% increase in AUC and Cmax for amitriptyline (25 mg per day) in 18 normal subjects (9 male; 9 female) receiving 200 mg/day of topiramate. Some subjects may experience a large increase in amitriptyline concentration in the presence of topiramate and any adjustments in amitriptyline dose should be made according to the patient's clinical response and not on the basis of plasma levels. Sumatriptan: Multiple dosing of topiramate (100 mg every 12 hs) in 24 healthy volunteers (14 M, 10 F) did not affect the pharmacokinetics of single dose sumatriptan either orally (100 mg) or subcutaneously (6 mg). Similarly, a 1 mg subcutaneous dose of topiramate (200 mg/day) in 24 healthy volunteers (12 M, 12 F) did not affect the pharmacokinetics of propranolol following daily 160 mg doses. Therefore, patients receiving risperidone in combination with topiramate should be closely monitored for clinical response. Propranolol: Multiple dosing of topiramate (200 mg/day) in 34 healthy volunteers (17 M, 17 F) did not affect the pharmacokinetics of propranolol following daily 160 mg doses. Propranolol doses of 160 mg/day in 39 volunteers (27M, 12F) did not affect the pharmacokinetics of propranolol following daily 160 mg doses. A 100 mg daily dose of topiramate in the same study. Other: Concomitant use of TOP AMAX®, a carbonic anhydrase inhibitor, with other carbonic anhydrase inhibitors, e.g., acetazolamide or dichlorphenamide, may create a physiological environment that increases the risk of renal stone formation, and should therefore be avoided. Drug/Laboratory Tests Interactions: There are no known interactions of topiramate with commonly used laboratory tests. Carcinogenesis, Mutagenesis, Impairment of Fertility: An increase in urinary bladder tumors was observed in mice given topiramate (20, 75, and 300 mg/kg) in the diet for 21 months. The elevated bladder tumor incidence, which was statistically significant in males and females receiving 300 mg/kg, was primarily due to the increased occurrence of a smooth muscle tumor considered histomorphologically unique to mice. Plasma exposures in mice receiving 300 mg/kg were approximately 0.5 to 1 times steady-state exposures measured in patients receiving topiramate monotherapy at the recommended human dose (RHD) of 400 mg, and 1.5 to 2 times steady-state topiramate exposures in patients receiving 400 mg of topiramate plus phentolamine. The relevance of this finding to human carcinogenic risk is uncertain. No evidence of carcinogenicity was seen in rats following oral administration of topiramate for 2 years at doses up to 120 mg/kg (approximately 3 times the RHD on a mg/m2 basis). Topiramate did not demonstrate genotoxic potential when tested in a battery of in vitro and in vivo assays. Topiramate was not mutagenic in the Ames test or the in vitro mouse lymphoma assay; it did not increase unscheduled DNA synthesis in rat hepatocytes in vitro; and it did not increase chromosomal aberrations in human lymphocytes in vitro or in rat bone marrow in vivo. No adverse effects on male or female fertility were observed in rats at doses up to 100 mg/kg (2.5 times the RHD on a mg/m2 basis). Topiramate did not demonstrate developmental toxicity when tested in a rat embryo/fetal development study with a postnatal component. Topiramate demonstrated selective developmental toxicity, including teratogenicity, in experimental animal studies. When oral doses of 20, 100, or 500 mg/kg were administered to pregnant mice during the period of organogenesis, the incidence of fetal malformations (primarily craniofacial defects) was increased at all doses. The low dose is approximately 0.2 times the recommended human dose (RHD=400 mg/day) on a mg/m2 basis. Fetal body weights and skeletal ossification were reduced at 500 mg/kg in conjunction with decreased maternal body weight gain. In rat studies (oral doses of 20, 100, and 500 mg/kg or 0.2, 2.5, 30, and 400 mg/mL), the frequency of limb malformations (ectrodactyly, micromelia, and amelia) was increased among the offspring of dams treated with 400 mg/kg (10 times the RHD on a mg/m2 basis) or greater during the organogenesis period of pregnancy. Embryotoxicity (reduced fetal body weights, increased incidence of structural variations) was observed at doses as low as 20 mg/kg (0.5 times the RHD on a mg/m2 basis). Clinical signs of maternal toxicity were seen at 400 mg/kg and above, and maternal body weight gain was reduced during treatment with 100 mg/kg or greater. In rabbit studies (20, 60, and 180 mg/kg or 10, 35, and 120 mg/kg orally during organogenesis), embryo/fetal mortality was increased at 35 mg/kg (2 times the RHD on a mg/m2 basis) or greater, and teratogenic effects (primarily rib and vertebral malformations) were observed at 120 mg/kg (6 times the RHD on a mg/m2 basis). Evidence of maternal toxicity (decreased body weight gain, clinical signs, and/or mortality) was seen at 35 mg/kg and above. When female rats were treated during the latter part of gestation and throughout lactation (0.4, 4, 20, and 100 mg/kg or 2, 20, and 200 mg/kg), offspring exhibited decreased viability and delayed physical development at 200 mg/kg (5 times the RHD on a mg/m2 basis) and reductions in pre- and/or postweaning body weight gain at 2 mg/kg (0.05 times the RHD on a mg/m2 basis) and above. Maternal toxicity (decreased body weight gain, clinical signs) was evident at 100 mg/kg or greater. In a rat embryo/fetal development study with a postnatal component (0.2, 2.5, 30, or 400 mg/kg during organogenesis; noted above), pups exhibited delayed physical development at 400 mg/kg (10 times the RHD on a mg/m2 basis) and persistent reductions in body weight gain at 30 mg/kg (1 times the RHD on a mg/m2 basis) and higher. There are no studies using TOPAMAX® in pregnant women. TOPAMAX® should be used during pregnancy only if the potential benefit outweighs the potential risk to the fetus. In postmarketing experience, cases of hypospadias have been reported in male infants exposed in utero to topiramate, with or without other anticonvulsants; however, a causal relationship with topiramate has not been established. Labor and Delivery: In studies of rats where dams were allowed to deliver pups naturally, no drug-related effects on gestation length or parturition were observed at dosage levels up to 200 mg/kg/day. The effect of TOPAMAX® on labor and delivery in humans is unknown. Nursing Mothers: Topiramate is excreted in the milk of lactating rats. The excretion of topiramate into human milk has not been evaluated in controlled studies. Limited observations in patients suggest an extensive secretion of topiramate into breast milk. Since many drugs are excreted in human milk, and because the potential for serious adverse reactions in nursing infants to TOPAMAX® is unknown, the potential benefit to the mother should be weighed against the potential risk to the infant when considering recommendations regarding nursing. Pediatric Use: Topiramate is associated with metabolic acidosis. Chronic untreated metabolic acidosis in pediatric patients may cause osteomalacia/rickets and may reduce growth rates. A reduction in growth rate may eventually decrease the maximal height achieved. The effect of topiramate on growth and bone-related sequelae has not been systematically investigated (see WARNINGS). Safety and effectiveness in pediatric patients have not been established for the prophylaxis treatment of migraine headache. Geriatric Use: In clinical trials, 3% of patients were over 60. No age related difference in effectiveness or adverse effects were evident. However, clinical studies of topiramate did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently than younger subjects. Dosage adjustment may be necessary for elderly patients with impaired renal function (creatinine clearance rate ≤ 70 mL/min/1.73 m2) due to reduced clearance of topiramate (see CLINICAL PHARMACOLOGY and DOSAGE AND ADMINISTRATION in the full PI). Race and Gender Effects: Evaluation of effectiveness and safety in clinical trials has shown no race or gender related effects. ADVERSE REACTIONS: The data described in the following section were obtained using TOPAMAX® (topiramate) Tablets. Migraine: In the four multicenter, randomized, double-blind, placebo-controlled, parallel group migraine prophylaxis clinical trials, most of the adverse events with topiramate were mild or moderate in severity. Most adverse events occurred more frequently during the titration period than during the maintenance period. Table 1 includes those adverse events reported for patients in the placebo-controlled trials where the incidence rate in any topiramate treatment group was at least 2% and was greater than that for placebo patients.
Table 1: Incidence of Treatment-Emergent Adverse Events in Placebo-Controlled, Migraine Trials Where Rate Was ≥2% in Any Topiramate Group and Greater than the Rate in Placebo-Treated Patients. 

<table>
<thead>
<tr>
<th>Body System/Adverse Event</th>
<th>Placebo (N=540)</th>
<th>Topiramate 100 (N=235)</th>
<th>Topiramate 200 (N=222)</th>
<th>Topiramate 400 (N=218)</th>
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</thead>
<tbody>
<tr>
<td>Adverse Event</td>
<td>Number of Patients</td>
<td>Number of Patients</td>
<td>Number of Patients</td>
<td>Number of Patients</td>
</tr>
<tr>
<td>Body as a Whole</td>
<td>131</td>
<td>136</td>
<td>137</td>
<td>136</td>
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<tr>
<td>Central &amp; Peripheral Nervous System Disorders</td>
<td>27</td>
<td>30</td>
<td>32</td>
<td>32</td>
</tr>
<tr>
<td>Mood Problems</td>
<td>27</td>
<td>30</td>
<td>32</td>
<td>32</td>
</tr>
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<td>Urinary Incontinence</td>
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<td>Other Adverse Events Observed During Migraine Clinical Trials:</td>
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| Topiramate overdose has resulted in severe metabolic acidosis, hepatic failure (including fatalities), hepatitis, maculopathy, pancreatitis, pemphigus, and renal tubular acidosis. 

Drug Abuse and Dependence: The abuse and dependence potential of TOPAMAX® has not been evaluated in human studies.

Overdose: Overdoses of TOPAMAX® have been reported. Signs and symptoms included convulsions, drowsiness, speech disturbance, blurred vision, diplopia, mentation impaired, lethargy, abnormal coordination, stupor, hypotension, abdominal pain, agitation, dizziness, and depression. The clinical consequences were not severe in most cases, but deaths have been reported after poly-drug overdoses involving TOPAMAX®.

Topiramate overdose has resulted in severe metabolic acidosis (see WARNINGS).

A patient who ingested a dose between 96 and 110 g topiramate was admitted to hospital with coma lasting 20-24 hours followed by full recovery after 3 to 4 days.

In acute TOPAMAX® overdose, if the ingestion is recent, the stomach should be emptied immediately by lavage or by induction of emesis. Activated charcoal has been shown to adsorb topiramate in vitro. Treatment should be appropriately supportive. Hemodialysis is an effective means of removing topiramate from the body.

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Revised April 2008 7517115MB 0277398MB
most out of it to automate more and more to where you’re tak-
ing the human error out of play.”

But workflow is just part of the equation. “The endgame for
these EMR technologies is not just the efficiencies. It’s really
can you improve the care,” Dr. Crow says. By looking at hyper-
tension metrics, the doctors were able to compare scores with
each other and with accepted standards of care. “Some of our
new doctors are just now starting to get quality data for the first
time in their careers.”

This information, such as blood pressure, cholesterol, and
hemoglobin A1c levels of diabetics, also helps the practice
demonstrate quality. “That’s where the endgame is, and that’s
what I show the insurance companies when I’m negotiating con-
tracts,” says Dr. Crow.

Integration is Key

It was not the EMR in itself, but the integration with practice
management and add-ons like clinical decision support and elec-
tronic charge capture that turned around the Austin, Tex., prac-
tice of McHorse Foster and Nutson. Internist and
gastroenterologist Thomas McHorse, MD, says the EMR has
been a break-even proposition at best, although financial per-
formance has taken off since he and his partners replaced their
early-1990s practice management system with iMedica Patient
Relationship Manager in September 2006.

Bruce Riegel, an independent consultant who helped the doc-
tors implement the system, says the practice charged 40 percent
more Level 4 and 5 visits, simply because of better documenta-
tion to support billing. “They are documenting a better record,”
Mr. Riegel says. “They increased their services by well over
$100,000,” a significant amount for a three-physician group.

“It takes longer to write good notes,” says Dr. Peter Nutson.
But they no longer are misplacing superbills in charts, a major
cause of lost revenue prior to the EMR.

The practice also is saving $2,000 a month in document stor-
age costs and $1,000 in paper and printing expenses from
automating numerous processes.

The physicians carry portable, wireless “tablet” computers
with them into exam rooms to review patient records, chart
encounters, enter orders, and send electronic charge slips to the clerical staff. Dr. McHorse says patient documentation is done before the patient leaves the office about 95 percent of the time.

The doctors perform some lab work in the office. With the EMR, the doctor enters the order; and alerts are sent to nurses and medical assistants, who then can prepare the tests. The office lab feeds into the EMR, and the practice has interfaced with its main outside lab, Clinical Pathology Laboratories, to receive results from the outside service. The practice has reminders built into the EMR system, helping assure that patients get regular examinations related to their age, gender, and chronic conditions.

Yes, there are some downsides to the switch. Dr. McHorse, who is 67, does not like having to break eye contact with the patient to work on his tablet PC. “I think it’s more of a problem for the doctor than for the patient,” particularly an older practitioner like himself, he says.

“Part of the skill of being a physician is nonverbal,” Dr. Nutson adds. “It just takes time” for patients to get comfortable with doctors’ carrying computers into the exam room, but they seem to have adjusted. “Most of the reaction to our going electronic has been positive,” he says.

McHorse Foster and Nutson went digital without having to shut down the office and stop seeing patients, but nearly anyone who has been through the transition will say there is at least a short-term slowdown in patient volume. “Everyone I talk to tells me it’s about a six-month productivity decline,” Mr. Slocum, the Philadelphia-area consultant, reports.

Practices often choose to automate in small bits, perhaps starting with electronic charge capture, online reference tools, automatic generation of referral letters, or a new billing system capable of sending standard HIPAA transactions without the need for a claims clearinghouse. One of the more popular standalone applications for physician practices is e-prescribing.

**The Move to E-prescribing**

Part of the reason for the enthusiasm is the public’s apparent understanding of the issues. There is a reason why people joke about doctors’ handwriting. Who hasn’t gotten an indecipherable
paper prescription at one point or another?
Perhaps it is a symptom of a celebrity-crazed society, but there
seemed to be genuine concern about patient safety when news
emerged about a recent dosing error that nearly killed the new-
born twins of actor Dennis Quaid. “Patients feel powerless in
this,” says Bevey Miner, executive director of the National E-

The MGMA says that the typical practice wastes $15,700 per physician
each year on prescription-related doctor and staff time. That works out to
$8.8 billion nationally for the 563,000 office-based practicing physicians.

Prescribing Patient Safety Initiative (NEPSI) and a vice presi-
dent of ambulatory IT vendor Allscripts.
In forming NEPSI in January 2007, Chicago-based Allscripts
and other technology partners pledged to spend at least $100
million over five years to provide free e-prescribing software,
called eRx Now, to any U.S. physician. Doctors can sign up at
www.nationalerx.com, in a process Ms. Miner says takes about
15 minutes, and one physician can sign up an entire practice,
including office staff, to handle refill processing.
This year, the MGMA, the American Academy of Family
Physicians, and the American College of Cardiology launched a
Web portal at www.getrxconnected.com to help physicians con-
vert to e-prescribing. Among the features is a tool to help deter-
mine if existing software meets the new CMS regulations and a
personalized report for practices to request an electronic connec-
tion to pharmacies through their IT vendors.
But even those who are using these services may not be using
them to their best advantage. Groups involved in the GetRxCon-
nected portal estimate that 150,000 prescribers are sending elec-
tronic faxes to pharmacies through their EHRs and other
software. One vendor, Sage Software Healthcare, says that 40
percent of scripts generated by its EHR customers are sent by
fax rather than electronic data interchange, and many others are
printed for the patient. This necessitates an extra round of data
entry at the pharmacy—another opportunity for errors—and
skips real-time formulary checks, leaving open the possibility of a call-back.

Physicians may balk at making the switch because they don’t believe a computerized system can be as fast as the time-honored process of scratching out a drug order on a pad of paper. “The laws of physics dictated that there is no technology faster than scribbling down something on a piece of paper,” says Michael Burger, director of clinical project management at Sage. “The cost benefit for a physician to use e-prescribing is questionable” on the surface, he says.

But Mr. Burger says that changes when physicians see the total cost of paper prescribing to the practice. In fact, the MGMA says that the typical practice wastes $15,700 per physician each year on prescription-related doctor and staff time. That works out to $8.8 billion nationally for the 563,000 office-based practicing physicians.

Louisiana, notorious for high health costs and poor outcomes even before Hurricanes Katrina and Rita, is spending $1.2 million this year to provide wireless e-prescribing devices and service to 500 Medicaid providers. The state expects this investment to save $4.8 million annually, through reduced duplication of drugs, greater generic utilization, and avoidance of harmful interactions, according to published reports.

The savings, e-prescribing advocates say, come from reduced callbacks from pharmacies seeking clarification on handwriting or dosage, or for formulary issues. “These calls are what slow the physician down,” says Kevin Hutchinson, president and chief executive of e-Rx vendor Prematics.

Mr. Hutchinson, the former CEO of e-prescribing connectivity network SureScripts, says his new company and most of its competitors not only are on the SureScripts network to link to chain and community pharmacies, but also connect with RxHub, a joint venture of the nation’s largest pharmacy benefit management companies that helps users check patient eligibility at the point of care.

Again, no technology is perfect, and although the list of excuses for avoiding e-prescribing may be shrinking, it still exists. Mr. Slocum believes PHRs, consumerism, and e-prescribing are among the many “diversions” people are trying rather
than promoting more comprehensive solutions. “It feels to me that we ought to be focused on the main goal, which is getting docs on EHRs,” he says.

“[E-prescribing] creates more work if it’s not integrated into the chart in some way,” Mr. Slocum says. “The logistics of that are not very good.” He says some physicians have also expressed concern about greater liability exposure if they have the fill information.

The complexity and cost of implementing IT systems, particularly EHRs, have spurred interest in standalone applications that may or may not be part of an interoperable system in the future—particularly among the physician population. “Too

Is the Time Right for E-prescribing?

Forces seem to be aligning to make 2008 the year that electronic prescribing explodes into the healthcare mainstream.

At the end of 2007, e-prescribing connectivity network SureScripts said its volume would triple this year to about 100 million new prescriptions and refills. Although that is a big number, it represents only about 7 percent of all scripts written in the U.S.

“Still, in anybody’s book, when it triples, that’s a good sign,” says Thomas E. Sullivan, MD, an internist from Danvers, Mass., who serves as chief strategic officer of Rockville, Md.-based e-prescribing vendor DrFirst.

In addition, the SureScripts forecast was based on conditions as they existed at the end of 2007. Several recent developments could accelerate growth.

The Drug Enforcement Agency (DEA) is working to lift its long-standing ban on electronic prescriptions for controlled substances. The agency tentatively lists September 2008 as the end of a 90-day public comment period on a forthcoming proposal—with a final rule to follow several months later—but some with DEA oversight, including Health and Human Services (HHS) Secretary Michael O. Leavitt and the Senate Judiciary Committee, have been pushing the agency to have the final rule change in place by midyear.

Currently, prescriptions for Schedule III, IV, and V substances can be faxed but not sent electronically, forcing physicians with technology to separate their orders, a cumbersome process. This also sets
“high’ is always relative to the buyer,” suggests Vinson Hudson, an Austin, Tex.-based physician practice management software market analyst. “If the return on investment is 10 times in two, three, or four years, it probably is worth the upfront cost.

Sometimes it takes a leap of faith. “When we did it, we worried about the cost,” admits ABCD Pediatrics office manager Ms. Waltemath. “You have to make sacrifices.”

The practice gave up profit-sharing for a year and put the money toward purchasing the EMR, then took out a loan for the balance, but the decision paid off. “Just with the increased revenue in the first year, we made enough money to replace the profit sharing,” Ms. Waltemath says.

up a potential conflict with a Medicare rule to take effect in 2009 that effectively would outlaw electronic faxes. (See Chapter 2.)

“It’s a huge hurdle because no physician wants to write only part of his or her prescriptions electronically,” says Bevey Miner, executive director of the National E-Prescribing Patient Safety Initiative (NEPSI), a free e-prescribing access program led by healthcare technology vendor Allscripts.

“There is no doubt” that the current ban has kept many doctors from moving to e-prescribing, according to Kevin Hutchinson, president and chief executive of e-Rx vendor Prematics. “Docs don’t want to have to think about [which drugs are on] Schedule III, IV, V,” explains Hutchinson. “They just put the device down.”

Ms. Miner has a “strong belief” that Congress will act this year to give HHS the authority to mandate e-prescribing for Medicare. Based on pending legislation, electronic prescribing could become the rule by 2010. Some states are pushing to outlaw paper scripts as well.

On the consumer side, SureScripts launched a public-awareness campaign in April to highlight the patient-safety benefits and convenience of e-prescribing. Expect to see “e-prescriptions filled here” and “give your prescriptions a head start” signage at some of the 95 percent of pharmacies nationwide that are certified on the SureScripts Pharmacy Health Information Exchange to accept electronic scripts.

Working with several physician organizations, SureScripts has set up a Website at www.getrxconnected.com for doctors’ offices to learn more about the technology. A companion consumer site is at www.learnabouteprescriptions.com.