What Does It Take To be Prepared?

Without the threat of a snowstorm or hurricane, or a Code Orange security advisory looming on the horizon, it may only be human to ignore disaster plans. However, while emergency planning takes time, energy, and money, it proves invaluable when a disaster actually strikes.

Fast Facts

- *The word "disaster" may bring to mind television coverage of hurricanes and other major storms. But 88 percent of the emergencies that interrupt business continuity are localized incidents, such as a broken water main or fire. Page 11.*
- *It's important to establish open communication with the health departments in order to get accurate information about a current health situation or crisis. Most offer healthcare providers a 24-hour telephone number for physicians to call. Page 23.*
- *Preparations made for a major disaster or crisis will pay off when well-trained staff respond expertly to everyday emergencies. Page 26.*

It's really easy to put planning off until tomorrow, next week, next month, then next year; and if something really bad happens, you're caught unprepared," says Rossanne M. Philen, MD, Medical Director for the Epidemic Information Exchange (*EPI-X*) of the Centers for Disease Control.

Physicians can't afford to be in that situation. In addition to their own families, they have patients, employees, co-workers, and communities relying on their expertise in an emergency.

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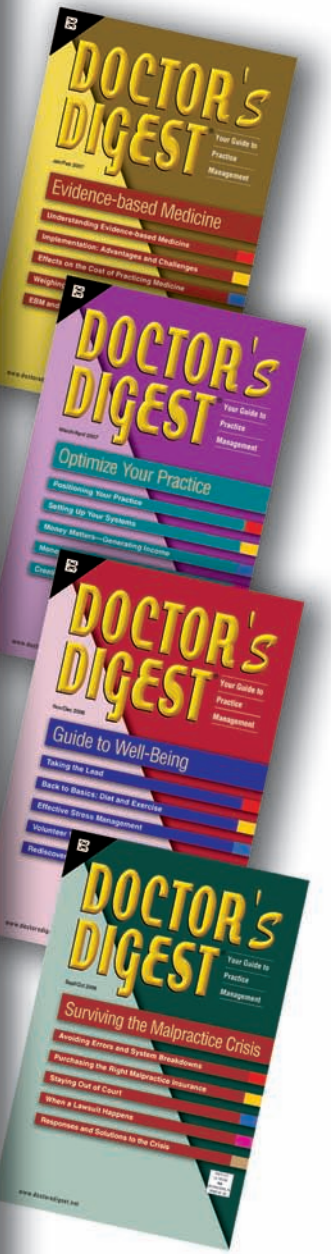

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"Doctors have unique needs because, in a large event, doctors and other first responders have to be there," says Bob Boyd, President and CEO of Agility Recovery Solutions, a company that "rescues" businesses after disasters and guarantees a return to operations within 48 hours. "[Doctors'] businesses really have to get back up and running. There are some businesses that don't necessarily have to be available the next day," he says.

> **"I think doctors** are becoming more prepared," says David Markenson, MD, Senior Research Scientist at the National Center for Disaster Preparedness at Columbia University. "But the level of preparedness is still far below where it needs to be on both fronts—the personal preparedness that the physician and their families perform so they can be ready to help others, and the preparedness in the office to function in a disaster setting."

Even if they are not treating the victims of a natural or other disaster, physicians and their staffs are on the frontlines dealing with the "worried well." Before disaster even strikes, physicians must fit disaster and emergency planning into their overall healthcare plan for their patients. This planning must include how patients will get prescriptions or other critical care during an emergency situation.

In some types of emergencies, such as an infectious disease outbreak or bioterrorist attack, physicians may play a role in detecting the situation as well as responding to it. It was a physician, infectious disease specialist Larry Bush, MD, who first suspected that a Florida photo editor's meningitis was due to anthrax, not the more common listeria or pneumococcus. He was also among the first who suspected bioterrorism, rather than an "isolated incident."

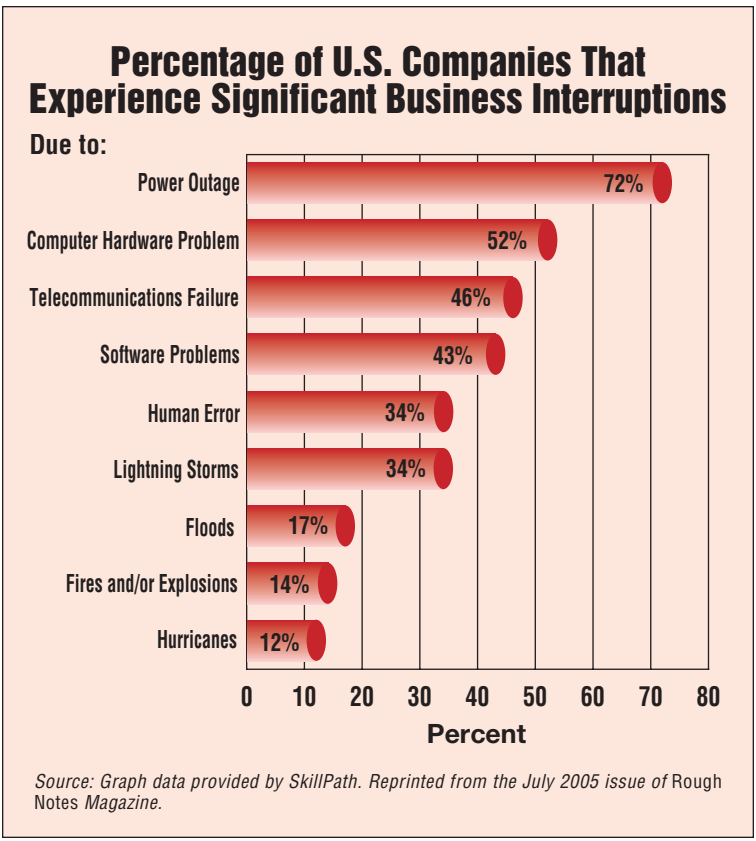
Hospitals, physicians' offices, and other healthcare entities are getting the message. Communities across the nation have stepped up disaster planning efforts and expanded the range of possible events for which they have preparedness plans. But we all have a way to go, preparedness experts say.

"I think doctors are becoming more prepared," says David Markenson, MD, Chair of the American Red Cross Advisory Council on First Aid and Safety in New York City and Senior Research Scientist at the National Center for Disaster Preparedness of the Mailman School of Public Health at Columbia Uni-

versity. "But the level of preparedness is still far below where it needs to be on both fronts—the personal preparedness that the physician and their families perform so they can be ready to help others, and the preparedness in the office to function in a disaster setting. I think both need to be addressed."

Prepare for What?

When a doctor thinks about disasters that could temporarily close down his or her practice, storm reels on the Weather Channel may come to mind. An April 2006 Harris Interactive poll found that 72 percent of U.S. adults believe that hurricanes are the most destructive disasters, while 53 percent fear earthquakes



Source: Graph data provided by SkillPath. Reprinted from the July 2005 issue of Rough Notes *Magazine.*

and tornados are the most destructive. About 43 percent think terrorism is most destructive, and 37 percent rank floods as most destructive. As for which disasters people feel are likely to have an impact on them, 46 percent feel that tornados will affect them; severe snow or ice storms followed at 45 percent, then drought at 39 percent and terrorism at 39 percent.

According to a 2004 research report, nearly three-quarters of Americans are concerned that there may be another terrorist attack. However, only an estimated 24 percent of Americans have a family emergency preparedness plan (defined as having two days' worth of food and water, flashlight, portable radio, batteries, phone numbers, and meeting place established). Nearly two-thirds of Americans have made no emergency plans.

What many people don't realize is that more mundane emergencies can be as disastrous as a major weather event and just as disruptive to business continuity. According to SkillPath, a business training consultant firm, only 12% of all the disasters that businesses face are caused by the named storms.

"The other 88% of emergencies are localized disasters. Your neighbor's pipe burst and flooded your server room. Or it could be the accident down the street that downed a power pole," says Bob Boyd.

According to a 2004 research report published by Columbia University's National Center for Disaster Preparedness (*How Americans Feel About Terrorism and Security Three Years After September 11*), nearly three-quarters of Americans are concerned that there may be another terrorist attack. However, only an estimated 24 percent of Americans have a family emergency preparedness plan (defined as having two days' worth of food and water, flashlight, portable radio, batteries, phone numbers, and meeting place established). Nearly two-thirds of Americans have made no emergency plans.

The survey found that eight in 10 (81%) adults who say they are most likely to be directly impacted by snow and ice say they are somewhat or very prepared for those storms. However, for all other disasters, only a small proportion of those who may be impacted say they are personally prepared. Just under half of those who say they are impacted by tornados and drought (49%

and 48%, respectively) are somewhat or very prepared. Even after the recent hurricane seasons, only one-third of those who say a hurricane will have an impact on them say they are somewhat or very prepared. While this number is slightly better for those in the South (52%), only 39 percent of those in the East say they are somewhat or very prepared.

"We use the term 'disaster denial,'" says James W. Satterfield, Chief Operations Officer of Firestorm, a risk management consulting firm based in Golden, Colo.

But such preparations can make all the difference if disaster strikes. W. Anderson Baker, III, an insurance broker based in New Orleans, took nothing with him when he evacuated his home before Katrina hit the city. After the storm, he was faced with a slew of crises—moving to his late mother-in-law's house, finding a school for his children, finding bare necessities to get him through the disaster that followed the disaster.

But at least he didn't have to worry about keeping his business afloat. Just two months before the storm, Mr. Baker signed up as a client of Agility Recovery. As a result, he was able to face his personal challenges without worrying about whether his business would survive.

"Part of being able to deal successfully with that aftermath is doing some preparation up front," says Mr. Boyd of Agility Recovery. "When the disaster happens, you're not at your best. You're worried about a lot of things and not necessarily making good personal or business decisions because it's a crisis."

This can be especially important for physicians. "If primary care physician practices stay closed, not only does it hurt them financially, it also hurts the community," explains Paul Biddinger, MD, Chairman of the Massachusetts Medical Society Committee on Preparedness.

Begin With the Basics

An easy way for a doctor to start thinking about an emergency preparedness plan is to prepare the practice for threats that are specific to the area. Is your area earthquake prone? Are you near a chemical plant? Is your town susceptible to wildfires? Are you in a hurricane zone or do you experience frequent, severe winter storms?

"The same plan that works in Florida is not going to work in Montana. It's important to look at the local issues first, then work up to the state," says Dr. Philen.

Depending on the size of a community, a physician can contact the area's emergency preparedness managers in the local fire department or health department. Most community hospitals have some sort of preparedness plan for disasters, including pandemic flu, bioterrorism, or a mass casualty incident. Physicians

How prepared are you?

In 2006, a Harris Interactive poll asked respondents, "How prepared are you personally if the following were to occur?" In most cases, less than half of the respondents felt they were prepared for events they thought were likely in their area. The notable exception: snow and ice storms.

		Region			
	Total	**East**	**Midwest**	**South**	**West**
Snow and/or ice storms	**81%**	84%	81%	73%	80%
Tornados	**49%**	27%	66%	54%	26%
Drought	**48%**	52%	47%	46%	49%
Floods	**42%**	39%	41%	46%	41%
Wildfires	**38%**	23%	27%	36%	50%
Hurricanes	**35%**	39%	16%	52%	22%
Earthquakes	**29%**	17%	17%	21%	55%
Terrorism	**28%**	30%	23%	29%	30%
Mudslides	**21%**	7%	10%	29%	28%

Source: Harris Interactive www.harrisinteractive.com/harris_poll/index.asp?PID=666.

should take time to become familiar with their hospitals' surge capacity plan.

There are instances in disasters when the outpouring to help out can overwhelm a healthcare facility and make treating patients more complicated. If you have an agreement with your affiliated hospital to help provide extra support in an emergency, it's important to know where you are expected to report amid all the chaos. Find out the plan before disaster strikes.

"Physicians with a strong hospital component to their practice should know under what circumstances they would come in and be expected to provide care in a disaster situation," says Dr. Biddinger. "The worst case is when everyone comes to the emergency room department to help. The flood of physicians and other healthcare providers trying to help can cause a second phase of the disaster in the ER department."

The most important step a doctor can take is to develop an emergency operations plan, or EOP, says Anita Barry, MD, director of Boston's Public Health Commission. According to Dr. Barry, a physician's EOP should answer three basic questions in an emergency:

- Where do my staff and I go?
- What do my staff and I do?
- How do my staff and I do it?

"[An EOP] spells out actions a physician needs to take in an emergency," Dr. Barry explains. "It coordinates actions, guides the communications, and identifies ahead of time the resources and mutual aid agreements that may already be in place."

Having a plan will increase your staff's confidence during an emergency and knowing you have a plan will also help assure your patients. In the Columbia University report on how people feel about terrorism and preparedness, 82 percent of the survey respondents said they had confidence in the Centers for Disease Control, and 78 percent said they had confidence in the National Institutes of Health (NIH) and the Surgeon General to give them accurate and reliable information during a terrorist attack. However, the report concluded there has been a steady decline in the public's confidence in the healthcare system to respond to chemical, biological, or terrorist attack. In 2002, 53 percent expressed confidence in the healthcare system; in 2004, the number had

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 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.

MANAGING *Migraines* MAY REQUIRE MORE THAN A QUICK FIX.

Ask how frequent, disruptive migraines may impact her both during and between attacks. Choose TOPAMAX to help reduce migraine frequency.[1,2]

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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.

References: 1. Silberstein SD, Neto W, Schmitt J, Jacobs D, for the MIGR-001 Study Group. Topiramate in migraine prevention: results of a large controlled trial. *Arch Neurol.* 2004;61:490-495. **2.** Brandes JL, Saper JR, Diamond M, et al, for the MIGR-002 Study Group. Topiramate for migraine prevention: a randomized controlled trial. *JAMA.* 2004;291:965-973.

Life shouldn't always revolve around migraines.

TOPAMAX®
(topiramate) Tablets

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 March 2007 02M931BD

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Brief Summary of Full Prescribing Information for Migraine. CLINICAL STUDIES FOR OTHER INDICATIONS WILL HAVE DIFFERING ADVERSE EVENTS AND SAFETY CONCERNS. PLEASE SEE FULL PI FOR THIS INFORMATION REGARDING TOPAMAX® FOR EPILEPSY.

INDICATIONS AND USAGE

Migraine: TOPAMAX® (topiramate) Tablets and TOPAMAX® (topiramate capsules) 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.

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, diarrhea, 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 supraciliary 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. *Somnolence/Fatigue:* Fatigue and somnolence 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 cognitive function with lethargy or vomiting. In most cases, symptoms and signs abated with discontinuation of either drug. This adverse event is not due to a pharmacokinetic interaction. It is not known if topiramate monotherapy is associated with hyperammonemia. Patients with inborn errors of metabolism or reduced hepatic mitochondrial activity may be at an increased risk for hyperammonemia with or without encephalopathy. Although not studied, an interaction of topiramate and valproic acid may exacerbate existing defects or unmask deficiencies in susceptible persons. In patients who develop unexplained lethargy, vomiting, or changes in mental status, hyperammonemic encephalopathy should be considered and an ammonia level should be measured. Kidney Stones: As in the general population, the incidence of stone formation among topiramate treated patients was higher in men. Kidney stones have also been reported in pediatric patients. An explanation for the association of TOPAMAX® and kidney stones may lie in the fact that topiramate is a carbonic anhydrase inhibitor. Carbonic anhydrase inhibitors, e.g., acetazolamide or dichlorphenamide, promote stone formation by reducing urinary citrate excretion and by increasing urinary pH. The concomitant use of TOPAMAX® with other carbonic anhydrase inhibitors or potentially in patients on a ketogenic diet may create a physiological environment that increases the risk of kidney stone formation, and should therefore be avoided. Increased fluid intake increases the urinary output, lowering the concentration of substances involved in stone formation. Hydration is recommended to reduce new stone formation. Paresthesia: Paresthesia (usually tingling of the extremities), an effect associated with the use of other carbonic anhydrase inhibitors, appears to be a common effect of TOPAMAX®. Paresthesia was more frequently reported in the monotherapy epilepsy trials and migraine prophylaxis trials versus the adjunctive therapy epilepsy trials. In the majority of instances, paresthesia did not lead to treatment discontinuation. Adjustment of Dose in Renal Failure: The major route of elimination of unchanged topiramate and its metabolites is via the kidney. Dosage adjustment may be required in patients with reduced renal function (see **DOSAGE AND ADMINISTRATION** in the full PI). Decreased Hepatic Function: In hepatically impaired patients, topiramate should be administered with caution as the clearance of topiramate may be decreased. **Information for Patients:** Patients should be instructed to read the Patient Information before starting treatment with TOPAMAX® and each time their prescription is renewed. Patients taking TOPAMAX® should be told to seek immediate medical attention if they experience blurred vision, visual disturbances or periorbital pain. Patients, especially pediatric patients, treated with TOPAMAX® should be monitored closely for evidence of decreased sweating and increased body temperature, especially in hot weather. Patients, particularly those with predisposing factors, should be instructed to maintain an adequate fluid intake in order to minimize the risk of renal stone formation [see **PRECAUTIONS:** Kidney Stones, for support regarding hydration as a preventative measure]. Patients should be warned about the potential for somnolence, dizziness, confusion, difficulty concentrating, and visual effects and advised not to drive or operate machinery until they have gained sufficient experience on topiramate to gauge whether it adversely affects their mental performance, motor performance, and/or vision. Additional food intake may be considered if the patient is losing weight while on this medication. **Laboratory Tests:** Measurement of baseline and periodic serum bicarbonate during topiramate treatment is recommended (see **WARNINGS**). In double-blind trials hypokalemia defined as serum potassium decline below 3.5 mmol/L has been observed in 0.4% of subjects treated with topiramate compared to 0.1% of subjects treated with placebo. **Drug Interactions:** *In vitro* studies indicate that topiramate does not inhibit enzyme activity for CYP1A2, CYP2A6, CYP2B6, CYP2C9, CYP2C19, CYP2D6, CYP2E1 and CYP3A4/5 isozymes. **Other Drug Interactions: Digoxin:** In a single-dose study, serum digoxin AUC was decreased by 12% with concomitant TOPAMAX® administration. The clinical relevance of this observation has not been established. **CNS Depressants:** Concomitant administration of TOPAMAX® and alcohol or other CNS depressant drugs has not been evaluated in clinical studies. 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 exposure (AUC) to either component of the oral contraceptive. 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 can be decreased even in the absence of breakthrough bleeding. **Hydrochlorothiazide (HCTZ):** 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 C_{max} 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 C_{max} and mean $AUC_{0\text{-}12h}$ increased by 18% and 25%, respectively, while mean CL/F decreased 20% when metformin was co-administered with topiramate. Topiramate did not affect metformin t_{max}. 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 $AUC_{\tau,ss}$ of pioglitazone with no alteration in $C_{max,ss}$ was observed. This finding was not statistically significant. In addition, a 13% and 16% decrease in $C_{max,ss}$ and $AUC_{\tau,ss}$ respectively, of the active hydroxy-metabolite was noted as well as a 60% decrease in $C_{max,ss}$ and $AUC_{\tau,ss}$ 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 C_{max} 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 C_{max} 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 hrs) 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). **Risperidone:** There was a 25% decrease in exposure to risperidone (2 mg single dose) in 12 healthy volunteers (6 M, 6 F) receiving 200 mg/day of topiramate. 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) had no effect on the exposure to topiramate at a dose of 200 mg/day of topiramate. **Dihydroergotamine:** Multiple dosing of topiramate (200 mg/day) in 24 healthy volunteers (12 M, 12 F) did not affect the pharmacokinetics of a 1 mg subcutaneous dose of dihydroergotamine. Similarly, a 1 mg subcutaneous dose of dihydroergotamine did not effect the pharmacokinetics of a 200 mg/day dose of topiramate in the same study. **Others:** Concomitant use of TOPAMAX®, 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 phenytoin. 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/m^2 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/m^2 basis). **Pregnancy: Pregnancy Category C.** Topiramate has 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/m^2 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/kg), 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/m^2 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/m^2 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/m^2 basis) or greater, and teratogenic effects (primarily rib and vertebral malformations) were observed at 120 mg/kg (6 times the RHD on a mg/m^2 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 (0.2, 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/m^2 basis) and reductions in pre- and/or postweaning body weight gain at 2 mg/kg (0.05 times the RHD on a mg/m^2 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/m^2 basis) and persistent reductions in body weight gain at 30 mg/kg (1 times the RHD on a mg/m^2 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 post-marketing 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 in 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 with impaired renal function (creatinine clearance rate ≤ 70 mL/min/1.73 m^2) 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.[a] **Body System/**Adverse Event followed by Placebo (N=445) first, TOPAMAX® Dosage (mg/day) 50 (N=235) second, 100 (N=386) third, 200 (N=514) fourth. **Body as a Whole – General Disorders:** Fatigue 11, 14, 15, 19; Injury 7, 9, 6, 6; Asthenia 1, <1, 2, 2; Fever 1, 1, 1, 2; Influenza-Like Symptoms <1, <1, <1, 2; Allergy <1, 2, <1, <1; **Central & Peripheral Nervous System Disorders:** Paresthesia 6, 35, 51, 49; Dizziness 10, 8, 9, 12; Hypoaesthesia 2, 6, 7, 8; Language Problems 2, 7, 6, 7; Involuntary Muscle Contractions 1, 2, 2, 4; Ataxia <1, 1, 2, 1; Speech Disorders/Related Speech Problems <1, 1, <1, 2; **Gastro-Intestinal System Disorders:** Nausea 8, 9, 13, 14; Diarrhea 4, 9, 11, 11; Abdominal Pain 5, 6, 6, 7; Dyspepsia 3, 4, 5, 3; **Gastro-Intestinal System Disorders:** Dry Mouth 2, 2, 3, 5; Vomiting 2, 1, 2, 3; Gastroenteritis 1, 3, 3, 2; **Hearing and Vestibular Disorders:** Tinnitus 1, <1, 1, 2; **Metabolic and Nutritional Disorders:** Weight Decrease 1, 6, 9, 11; Thirst <1, 2, 2, 1; **Musculoskeletal System Disorders:** Arthralgia 2, 7, 3, 1; **Neoplasms:** Neoplasm NOS <1, 2, <1, <1; **Psychiatric Disorders:** Anorexia 6, 9, 15, 14; Somnolence 5, 8, 7, 10; Difficulty with Memory NOS 2, 7, 7, 11; Difficulty with Concentration/Attention 2, 3, 6, 10; Insomnia 5, 6, 7, 6; Anxiety 3, 4, 5, 6; Mood Problems 2, 3, 6, 5; Depression 4, 3, 4, 6; Nervousness 2, 4, 4, 4; Confusion 2, 2, 3, 4; Psychomotor Slowing 1, 3, 2, 4; Libido Decreased 1, 1, 1, 2; Aggravated Depression 1, 1, 2, 2; Agitation 1, 2, 2, 1; Cognitive Problems NOS 1, <1, 2, 2; **Reproductive Disorders, Female:** Menstrual Disorder 2, 3, 2, 2; **Reproductive Disorders, Male:** Ejaculation Premature 0, 3, 0, 0; **Resistance Mechanism Disorders:** Viral Infection 3, 4, 4, 3; Otitis Media <1, 2, 1, 1; **Respiratory System Disorders:** Upper Respiratory Tract Infection 12, 13, 14, 12; Sinusitis 6, 10, 6, 8; Pharyngitis 4, 5, 6, 2; Coughing 2, 2, 4, 3; Bronchitis 2, 3, 3, 3; Dyspnea 2, 1, 3, 2; Rhinitis 1, 1, 2, 2; **Skin and Appendages Disorders:** Pruritis 2, 4, 2, 2; **Special Sense Other, Disorders:** Taste Perversion 1, 15, 8, 12; Taste Loss <1, 1, 1, 2; **Urinary System Disorders:** Urinary Tract Infection 2, 4, 2, 4: Renal Calculus 0, 0, 1, 2; **Vision Disorders:** Vision Abnormal <1, 1, 2, 3; Blurred Vision[b] 2, 4, 2, 4; Conjunctivitis 1, 1, 2, 1: [a]Values represent the percentage of patients reporting a given adverse event. Patients may have reported more than one adverse event during the study and can be included in more than one adverse event category. [b]Blurred vision was the most common term considered as vision abnormal. Blurred vision was an included term that accounted for > 50% of events coded as vision abnormal, a preferred term. Of the 1,135 patients exposed to topiramate in the placebo-controlled studies, 25% discontinued due to adverse events, compared to 10% of the 445 placebo patients. The adverse events associated with discontinuing therapy in the topiramate-treated patients included paresthesia (7%), fatigue (4%), nausea (4%), difficulty with concentration/attention (3%), insomnia (3%), anorexia (2%), and dizziness (2%). Patients treated with topiramate experienced mean percent reductions in body weight that were dose-dependent. This change was not seen in the placebo group. Mean changes of 0%, -2%, - 3%, and - 4% were seen for the placebo group, topiramate 50, 100, and 200 mg groups, respectively. Table 2 shows adverse events that were dose-dependent. Several central nervous system adverse events, including some that represented cognitive dysfunction, were dose-related. The most common dose-related adverse events were paresthesia, fatigue, nausea, anorexia, dizziness, difficulty with memory, diarrhea, weight decrease, difficulty with concentration/attention, and somnolence.

Table 2: Incidence (%) of Dose-Related Adverse Events From Placebo-Controlled, Migraine Trials.[a] Adverse Event followed by Placebo (N=445) first, TOPAMAX® Dosage (mg/day) 50 (N=235) second, 100 (N=386) third, 200 (N=514) fourth. Paresthesia 6, 35, 51, 49; Fatigue 11, 14, 15, 19; Nausea 8, 9, 13, 14; Anorexia 6, 9, 15, 14; Dizziness 10, 8, 9, 12; Weight decrease 1, 6, 9, 11; Difficulty with Memory NOS 2, 7, 7, 11; Diarrhea 4, 9, 11, 11; Difficulty with Concentration/Attention 2, 3, 6, 10; Somnolence 5, 8, 7, 10; Hypoaesthesia 2, 6, 7, 8; Anxiety 3, 4, 5, 6; Depression 4, 3, 4, 6; Mood Problems 2, 3, 6, 5; Dry Mouth 2, 2, 3, 5; Confusion 2, 2, 3, 4; Involuntary Muscle Contractions 1, 2, 2, 4; Abnormal Vision <1, 1, 2, 3; Renal Calculus 0, 0, 1, 2. [a]The incidence rate of the adverse event in the 200 mg/day group was ≥ 2% than the rate in both the placebo group and the 50 mg/day group.

Other Adverse Events Observed During Migraine Clinical Trials: Topiramate, for the treatment of prophylaxis of migraine headache, has been administered to 1,367 patients in all clinical studies (includes double-blind and open-label extension). During these studies, all adverse events were recorded by the clinical investigators using terminology of their own choosing. To provide a meaningful estimate of the proportion of individuals having adverse events, similar types of events were grouped into a smaller number of standardized categories using modified WHOART dictionary terminology. The following additional adverse events that were not described earlier were reported by greater than 1% of the 1,367 topiramate-treated patients in the controlled clinical trials: **Body as a Whole:** Pain, chest pain, allergic reaction. **Central & Peripheral Nervous System Disorders:** Headache, vertigo, tremor, sensory disturbance, migraine aggravated. **Gastrointestinal System Disorders:** Constipation, gastroesophageal reflux, tooth disorder. **Musculoskeletal System Disorders:** Myalgia. **Platelet, Bleeding, and Clotting Disorders:** Epistaxis. **Reproductive Disorders, Female:** Intermenstrual bleeding. **Resistance Mechanism Disorders:** Infection, genital moniliasis. **Respiratory System Disorders:** Pneumonia, asthma. **Skin and Appendages Disorders:** Rash, alopecia. **Vision Disorders:** Abnormal accommodation, eye pain. **Postmarketing and Other Experience:** In addition to the adverse experiences reported during clinical testing of TOPAMAX®, the following adverse experiences have been reported worldwide in patients receiving TOPAMAX® post-approval. These adverse experiences have not been listed above and data are insufficient to support an estimate of their incidence or to establish causation. The listing is alphabetized: bullous skin reactions (including erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis), hepatic failure (including fatalities), hepatitis, pancreatitis, pemphigus, and renal tubular acidosis.

DRUG ABUSE AND DEPENDENCE: The abuse and dependence potential of TOPAMAX® has not been evaluated in human studies.

OVERDOSAGE

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 March 2007 7517114MB

fallen to 28 percent. Even fewer—23 percent—said the health-care system was prepared for a pandemic flu situation.

While patients may not trust the system, they do trust their doctors. A 2004 study conducted for the British Medical Association found that 91 percent of the public trusted their doctors to tell them the truth, followed by teachers, professors, and judges. As a result, physicians have an educational opportunity—even a responsibility—to teach patients about the importance of being prepared for the unexpected.

Having a consulting firm oversee disaster preparations can also relieve staff of burdensome paperwork. "There is a myriad of accrediting bodies out there that don't always mesh with each other. By having someone from the outside come in and make these assessments for you and keep you up to date with what's going on, you have less to worry about," says Ms. Olivera-Mustard.

Close encounters with hurricanes in Florida and the Caribbean have made Dr. Asperilla, MD, vigilant about sending the emergency preparedness message to his patients. "I tell my patients to have emergency medications and emergency bags ready because anything can happen in this hurricane and tornado belt," says Dr. Asperilla. He also keeps plenty of brochures in his office outlining what to do in case of hurricanes and where the nearest shelters are.

For physicians who do not relish diving into an emergency preparedness office plan on their own, Dr. Philen recommends joining with other physicians in a group practice or at a hospital or local medical society, to work on plans for how to handle it as a group. This group approach can also afford some extra flexibility in the plan.

Delegating the project to a risk management consulting firm is another effective way to get the job done. Liz Olivera-Mustard, Director of Online Services for Total Compliance Solutions, a New England-based consultant firm with 3,000 medical clients, both large and small, says her firm helps practices on a wide range of projects, from a simple fire safety plan to a full-blown Fire Safety and Disaster Plan complete with training and drills that meet Joint Commission requirements. Depending on the complexity of the disaster plan, the assessment can take from

half a day to three days with periodic follow-up visits.

Ms. Olivera-Mustard says clients often cite time savings as the main reason to outsource disaster preparations, but she points out that having a consulting firm take over can also relieve staff of burdensome paperwork. "There is a myriad of accrediting bodies out there that don't always mesh with each other; so it makes it really difficult for a person who has very little time to pick something up and put a program together. By having someone from the outside come in and make these assessments for you and keep you up to date with what's going on, you have less to worry about," says Ms. Olivera-Mustard.

The Post-disaster Disaster

One common lesson learned from the September 11 attack, the Northeast power outage of August 2003, and Hurricane Katrina is that continuity of communication is critical. "No matter how good your plans are, it's not going to be perfect because the disaster is never going to happen the way you think it's going to happen. The only certainty is uncertainty," says Mike Rosenfelt, Executive Vice President of MessageOne, a business continuity and e-mail management company in Austin, Tex.

After Hurricane Katrina, W. Anderson Baker, an insurance broker based in New Orleans, heard his cellphone make a strange sound it had never made before. As he tinkered with the buttons, he realized that someone was trying to send him his very first text message. He fiddled with his phone and discovered how to read and reply. His partner had sent him a text message to see if he were alive.

In the most common scenario, even if phone service is unavailable because both land and cell lines are jammed with too many calls, data services may remain functional. "Every disaster is unique; so it's critical to plan for having as many potentially viable solutions as possible in place; you don't know which will go down, and of those that do, you never know the order and timing for when they come back into service," says Paul D'Arcy, Vice President of Marketing for MessageOne. His biggest task for his clients is assessing risk, understanding all the threats, and educating clients on how to mitigate those threats.

Experts agree that it's important to establish open communi-

cation with the health departments in order to get accurate information about a current health situation or crisis. When Boston had a measles outbreak in 2006, Dr. Barry says that many inaccurate rumors started circulating. One was that pregnant women shouldn't go into the Hancock Tower, where the measles cases had started. People at the health commission had to set the record straight and publicize guidelines and appropriate measures to protect patients.

If you should encounter a patient with unusual symptoms for any of the "notifiable" diseases the CDC requires health providers to report, or something entirely unfamiliar, this teamwork will be critical to diagnosing an outbreak or another public health emergency. "Our hospitals and physicians can call us 24/7. Most large health departments have such a service; if not, they are covered at night by the state. So there is always a 24-hour number for physicians and consultations," says Daniel Kuhles, MD, Assistant Director of the Division of Disease Control at the Nassau County Department of Health in New York.

"You can't initiate a point-of-distribution control measure where you give Cipro for anthrax or smallpox vaccine until you have a good idea of what it is. The threshold for that trigger is when something is so severe and has such serious consequences that you're going to initiate that control action quickly," explains

Questions to Ask When Making an Emergency Preparedness Plan

- How can I be a resource to my patients when their normal health care is not available?
- What if our Internet access and telephones go down?
- If our office is destroyed or not accessible, how will we access patient records?
- What happens if we need to evacuate the building?
- What emergencies are likely to happen in our area? Hurricanes, severe blizzards, earthquakes, power outages?
- What is our anticipated role in an emergency? Are we expected to report to our local hospital to help with urgent care? If so, who will replace me at the office?

Dr. Kuhles.

Local health departments should take their lead from the CDC so that everyone is working together "to send a clear message to the public on what precautions they need to take to address a public health crisis," says Cynthia Brown, public information officer at the Nassau County Department of Health. In the event of a public health emergency, the health department sets up points-of-distribution centers that are usually run using the medical reserve corps and physician volunteers.

In 2002, the Nassau County Health Department was in the hot seat when several cases of West Nile disease in humans were diagnosed on Long Island, including northwest Nassau County. Ms. Brown's office geared up and created a war room with dozens of phones, where over 100,000 calls were received from concerned residents. "We not only give advice, how to stay healthy, etc., but we also had to talk to the worried well to stop any potential panic," says Ms. Brown.

Preparation Pays Off

People may think of emergency drills as a mere disruption from the day's work. Similar to doing a fire drill, Dr. Philen says everybody gets annoyed having to leave their desks and go outside for 20 minutes. But the fact is that drills work. When the

- What will we do if a power outage occurs?
- If banks are closed for an extended period of time, how will employees get paid?
- How do we transition patients to healthcare facilities if ambulances are not available?
- Do we have personal protective equipment? Does staff know how to use it?
- Do we have good communication with the paramedics?
- Does the practice's physical layout promote respiratory hygiene?
- How can we separate the worried well from contagious patients?
- In case of an unusual outbreak, how do we handle patients and make sure they are dealt with in a particular order?
- If the doctor becomes ill, disabled, or even dies, who will replace that doctor and look after those patients?

alarm does go off, staff members know what to do. "The preparation you do for pandemic flu is just as handy for any other outbreak that would probably be more common and more likely for the typical physician to face. It's much more likely that something else will happen, like a big measles or chicken pox outbreak," says Dr. Philen.

The World Trade Center Evacuation Study, which was conducted by the Mailman School of Public Health at Columbia University in late 2002, surveyed former employees at the World Trade Center who evacuated the building on September 11, 2001, and escaped. According to Robyn R.M. Gershon, MHS, DrPh, the study's principal investigator, the findings shed light on how people behave in emergencies and help inform emergency responders about what to expect in future emergencies in public spaces.

"The preparation you do for pandemic flu is just as handy for any other outbreak that would probably be more common and more likely for the typical physician to face. It's much more likely that something else will happen, like a big measles or chicken pox outbreak," says Dr. Philen.

"One thing that was amazing to me was how people were able to piece together each little bit of information that they knew," says Dr. Gershon. "One person said, 'I know where there's another staircase, follow me,"' and then they got on the staircase, and another said, 'I know where this ends, follow me,' and then somebody got to the bottom and someone said, 'I know where you can get onto the street really fast.' Not everyone had to know everything, but enough had to know something."

The study showed that people generally make an effort to stay in a group, which could be to their benefit or their detriment. (For example, about two dozen people were led to the roof by a senior corporate executive. Judging from phone records, some people were unsure if this was the best choice, but followed anyway.) The other surprising finding from this event was that between one and four percent of respondents said they delayed leaving because they were trying to get permission from their supervisors and were afraid that, if they left without permission, it would affect their employment. "Those people who were

delayed were more likely to be injured as things evolved further into chaos," says Dr. Gershon.

Dr. Gershon's research revealed some recommendations: "Having announcements is incredibly important so that you can galvanize a bunch of people to go to the right exit," she says. Signage is another good way to ensure people have the right information. It's also important to make sure key people have training in emergency procedures. "Some airport executives are thinking about training people who work at airport shops to be able to do crowd control," says Dr. Gershon.

Since conducting the research, Dr. Gershon admits she's become hyper-vigilant, instinctively looking for an evacuation route whenever she is in a public space. However, she feels this is a good habit, especially for physicians. "I think that, both as an individual and as a physician for yourself and your family, you have to pay attention to exits when you're in those public use/assembly spaces. If something happens, you'll be the one to emerge from the crowd and emerge as the leader," says Dr. Gershon.