Proactive Measures

There is a fine line between alerting and alarming. According to James W. Satterfield, President-Chief Operations Officer of Firestorm Solutions, a risk management consulting firm based in Colorado, a lot of companies are struggling with the questions, "When do we tell our employees, and what do we tell them?"

While a physician doesn't want to alarm patients or staff by having daily pandemic briefings, waiting until the Centers for Disease Control or the federal government declares a pandemic would be too late to make the necessary preparations. Mr. Satterfield says that in disasters such as Hurricane Katrina, "we all become our own first responders." Businesses of all types—but especially medical practices—must be prepared.

Fast Facts

- *Although patients increasingly look to the Internet for health information, they often turn to their doctors to help them sift through the information. Staff may have to deal with a surge of phone calls and walk-ins with questions. Page 34.*
- *Joining forces with another physician's office is one way to help ensure that an office is not understaffed during an emergency. A "floating staff" may work half the day at one practice and in the afternoon switch to the other practice. Page 37.*
- *In a study, researchers found that health workers were more willing to respond to some types of disasters than others. For example, fewer were willing to respond to a smallpox epidemic (61%), a radiological event (57%), or a SARS outbreak (48%) than to a mass casualty incident (86%) or an environmental disaster (84%). Page 39.*

Master the Fine Art of Sleep

Prescribe LUNESTA first-line—for a full 7 to 8 hours of sleep

LUNESTA has been studied in large, well-controlled clinical trials in **all** of the following patient types:

- Patients With Insomnia Comorbid With Major Depressive Disorder
- Patients With Insomnia Comorbid With Generalized Anxiety Disorder
- Patients With Insomnia Comorbid With Rheumatoid Arthritis
- Patients With Insomnia Comorbid With Menopause

The failure of insomnia to remit after 7 to 10 days of treatment should be medically evaluated.

Any night or every night

Leave the rest to...

Lunesta® (eszopiclone)c
1, 2 AND 3 MG TABLETS

LUNESTA is indicated for the treatment of insomnia. In controlled outpatient and sleep laboratory studies, LUNESTA administered at bedtime decreased sleep latency and improved sleep maintenance. LUNESTA is not indicated for the treatment of depression, generalized anxiety disorder, rheumatoid arthritis, or menopause.

Important Safety Information

LUNESTA, like other hypnotics, has CNS-depressant effects. Because of the rapid onset of action, LUNESTA should only be ingested immediately prior to going to bed or after the patient has gone to bed and has experienced difficulty falling asleep. Patients should not take LUNESTA unless they are prepared to get a full night's sleep. As with other hypnotics, patients receiving LUNESTA should be cautioned against engaging in hazardous occupations requiring complete mental alertness or motor coordination (eg, operating machinery or driving a motor vehicle) after ingesting the drug, including potential impairment of the performance of such activities that may occur the day following ingestion of LUNESTA. In clinical trials, the most common adverse events associated with LUNESTA were unpleasant taste, headache, somnolence, dizziness, dry mouth, infection, and pain.

LUNESTA has been classified as a Schedule IV controlled substance. Sedative hypnotics have produced withdrawal signs and symptoms following abrupt discontinuation. The risk of abuse and dependence increases with the dose and duration of treatment and concomitant use of other psychoactive drugs. The risk is also greater for patients who have a history of alcohol or drug abuse or history of psychiatric disorders. These patients should be under careful surveillance when receiving LUNESTA or any other hypnotic. Sedative/hypnotic drugs should be administered with caution to patients exhibiting signs and symptoms of depression. Suicidal tendencies may be present in such patients, and protective measures may be required. Intentional overdose is more common in this group of patients; therefore, the least amount of drug that is feasible should be prescribed for the patient at any one time.

LUNESTA, like other hypnotics, may produce additive CNS-depressant effects when coadministered with other psychotropic medications, anticonvulsants, antihistamines, ethanol, and other drugs that themselves produce CNS depression. LUNESTA should not be taken with alcohol. Dosage adjustment may be necessary when LUNESTA is administered with other CNS-depressant agents because of the potentially additive effects.

Impaired motor and/or cognitive performance after repeated exposure or unusual sensitivity to sedative/hypnotic drugs is a concern in the treatment of elderly and/or debilitated patients. See dosage and administration in complete prescribing information.

Please see brief summary of complete prescribing information.

6SRZO412

Lunesta®
(eszopiclone)C
1, 2 AND 3 MG TABLETS

BRIEF SUMMARY

INDICATIONS AND USAGE

LUNESTA is indicated for the treatment of insomnia. In controlled outpatient and sleep laboratory studies, LUNESTA administered at bedtime decreased sleep latency and improved sleep maintenance.

CONTRAINDICATIONS

None known.

WARNINGS

Because sleep disturbances may be the presenting manifestation of a physical and/or psychiatric disorder, symptomatic treatment of insomnia should be initiated only after a careful evaluation of the patient. The failure of insomnia to remit after 7 to 10 days of treatment may indicate the presence of a primary psychiatric and/or medical illness that should be evaluated. Worsening of insomnia or the emergence of new thinking or behavior abnormalities may be the consequence of an unrecognized psychiatric or physical disorder. Such findings have emerged during the course of treatment with sedative/hypnotic drugs, including LUNESTA. Because some of the important adverse effects of LUNESTA appear to be dose-related, it is important to use the lowest possible effective dose, especially in the elderly (see **DOSAGE AND ADMINISTRATION in the Full Prescribing Information**).

A variety of abnormal thinking and behavior changes have been reported to occur in association with the use of sedative/hypnotics. Some of these changes may be characterized by decreased inhibition (e.g., aggressiveness and extroversion that seem out of character), similar to effects produced by alcohol and other CNS depressants. Other reported behavioral changes have included bizarre behavior, agitation, hallucinations, and depersonalization. Amnesia and other neuropsychiatric symptoms may occur unpredictably. In primarily depressed patients, worsening of depression, including suicidal thinking, has been reported in association with the use of sedative/hypnotics.

It can rarely be determined with certainty whether a particular instance of the abnormal behaviors listed above are drug-induced, spontaneous in origin, or a result of an underlying psychiatric or physical disorder. Nonetheless, the emergence of any new behavioral sign or symptom of concern requires careful and immediate evaluation.

Following rapid dose decrease or abrupt discontinuation of the use of sedative/hypnotics, there have been reports of signs and symptoms similar to those associated with withdrawal from other CNS-depressant drugs (see **DRUG ABUSE AND DEPENDENCE**).

LUNESTA, like other hypnotics, has CNS-depressant effects. Because of the rapid onset of action, LUNESTA should only be ingested immediately prior to going to bed or after the patient has gone to bed and has experienced difficulty falling asleep. Patients receiving LUNESTA should be cautioned against engaging in hazardous occupations requiring complete mental alertness or motor coordination (e.g., operating machinery or driving a motor vehicle) after ingesting the drug, and be cautioned about potential impairment of the performance of such activities on the day following ingestion of LUNESTA. LUNESTA, like other hypnotics, may produce additive CNS-depressant effects when coadministered with other psychotropic medications, anticonvulsants, antihistamines, ethanol, and other drugs that themselves produce CNS depression. LUNESTA should not be taken with alcohol. Dose adjustment may be necessary when LUNESTA is administered with other CNS-depressant agents, because of the potentially additive effects.

PRECAUTIONS

General

Timing Of Drug Administration: LUNESTA should be taken immediately before bedtime. Taking a sedative/hypnotic while still up and about may result in short-term memory impairment, hallucinations, impaired coordination, dizziness, and lightheadedness.

Use In The Elderly And/Or Debilitated Patients: Impaired motor and/or cognitive performance after repeated exposure or unusual sensitivity to sedative/hypnotic drugs is a concern in the treatment of elderly and/or debilitated patients. The recommended starting dose of LUNESTA for these patients is 1 mg (see **DOSAGE AND ADMINISTRATION in the Full Prescribing Information**).

Use In Patients With Concomitant Illness: Clinical experience with eszopiclone in patients with concomitant illness is limited. Eszopiclone should be used with caution in patients with diseases or conditions that could affect metabolism or hemodynamic responses.

A study in healthy volunteers did not reveal respiratory-depressant effects at doses 2.5-fold higher (7 mg) than the recommended dose of eszopiclone. Caution is advised, however, if LUNESTA is prescribed to patients with compromised respiratory function.

The dose of LUNESTA should be reduced to 1 mg in patients with severe hepatic impairment, because systemic exposure is doubled in such subjects. No dose adjustment appears necessary for subjects with mild or moderate hepatic impairment. No dose adjustment appears necessary in subjects with any degree of renal impairment, since less than 10% of eszopiclone is excreted unchanged in the urine.

The dose of LUNESTA should be reduced in patients who are administered potent inhibitors of CYP3A4, such as ketoconazole, while taking LUNESTA. Downward dose adjustment is also recommended when LUNESTA is administered with agents having known CNS-depressant effects.

Use In Patients With Depression: Sedative/hypnotic drugs should be administered with caution to patients exhibiting signs and symptoms of depression. Suicidal tendencies may be present in such patients, and protective measures may be required. Intentional overdose is more common in this group of patients; therefore, the least amount of drug that is feasible should be prescribed for the patient at any one time.

Information For Patients: Patient information is printed in the complete prescribing information.

Laboratory Tests: There are no specific laboratory tests recommended.

Drug Interactions

CNS-Active Drugs

Ethanol: An additive effect on psychomotor performance was seen with coadministration of eszopiclone and ethanol 0.70 g/kg for up to 4 hours after ethanol administration.

Paroxetine: Coadministration of single doses of eszopiclone 3 mg and paroxetine 20 mg daily for 7 days produced no pharmacokinetic or pharmacodynamic interaction.

Lorazepam: Coadministration of single doses of eszopiclone 3 mg and lorazepam 2 mg did not have clinically relevant effects on the pharmacodynamics or pharmacokinetics of either drug.

Olanzapine: Coadministration of eszopiclone 3 mg and olanzapine 10 mg produced a decrease in DSST scores. The interaction was pharmacodynamic; there was no alteration in the pharmacokinetics of either drug.

Drugs That Inhibit CYP3A4 (Ketoconazole): CYP3A4 is a major metabolic pathway for elimination of eszopiclone. The AUC of eszopiclone was increased 2.2-fold by coadministration of ketoconazole, a potent inhibitor of CYP3A4, 400 mg daily for 5 days. C_{max} and $t_{1/2}$ were increased 1.4-fold and 1.3-fold, respectively. Other strong inhibitors of CYP3A4 (e.g., itraconazole, clarithromycin, nefazodone, troleandomycin, ritonavir, nelfinavir) would be expected to behave similarly.

Drugs That Induce CYP3A4 (Rifampicin): Racemic zopiclone exposure was decreased 80% by concomitant use of rifampicin, a potent inducer of CYP3A4. A similar effect would be expected with eszopiclone.

Drugs Highly Bound To Plasma Protein: Eszopiclone is not highly bound to plasma proteins (52-59% bound); therefore, the disposition of eszopiclone is not expected to be sensitive to alterations in protein binding. Administration of eszopiclone 3 mg to a patient taking another drug that is highly protein-bound would not be expected to cause an alteration in the free concentration of either drug.

Drugs With A Narrow Therapeutic Index

Digoxin: A single dose of eszopiclone 3 mg did not affect the pharmacokinetics of digoxin measured at steady state following dosing of 0.5 mg twice daily for one day and 0.25 mg daily for the next 6 days.

Warfarin: Eszopiclone 3 mg administered daily for 5 days did not affect the pharmacokinetics of (R)- or (S)-warfarin, nor were there any changes in the pharmacodynamic profile (prothrombin time) following a single 25-mg oral dose of warfarin.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis: In a carcinogenicity study in Sprague-Dawley rats in which eszopiclone was given by oral gavage, no increases in tumors were seen; plasma levels (AUC) of eszopiclone at the highest dose used in this study (16 mg/kg/day) are estimated to be 80 (females) and 20 (males) times those in humans receiving the maximum recommended human dose (MRHD). However, in a carcinogenicity study in Sprague-Dawley rats in which racemic zopiclone was given in the diet, and in which plasma levels of eszopiclone were reached that were greater than those reached in the above study of eszopiclone, an increase in mammary gland adenocarcinomas in females and an increase in thyroid gland follicular cell adenomas and carcinomas in males were seen at the highest dose of 100 mg/kg/day. Plasma levels of eszopiclone at this dose are estimated to be 150 (females) and 70 (males) times those in humans receiving the MRHD. The mechanism for the increase in mammary adenocarcinomas is unknown. The increase in thyroid tumors is thought to be due to increased levels of TSH secondary to increased metabolism of circulating thyroid hormones, a mechanism that is not considered to be relevant to humans.

In a carcinogenicity study in B6C3F1 mice in which racemic zopiclone was given in the diet, an increase in pulmonary carcinomas and carcinomas plus adenomas in females and an increase in skin fibromas and sarcomas in males were seen at the highest dose of 100 mg/kg/day. Plasma levels of eszopiclone at this dose are estimated to be 8 (females) and 20 (males) times those in humans receiving the MRHD. The skin tumors were due to skin lesions induced by aggressive behavior, a mechanism that is not relevant to humans. A carcinogenicity study was also performed in which CD-1 mice were given eszopiclone at doses up to 100 mg/kg/day by oral gavage; although this study did not reach a maximum tolerated dose, and was thus inadequate for overall assessment of carcinogenic potential, no increases in either pulmonary or skin tumors were seen at doses producing plasma levels of eszopiclone estimated to be 90 times those in humans receiving the MRHD—i.e., 12 times the exposure in the racemate study.

Eszopiclone did not increase tumors in a p53 transgenic mouse bioassay at oral doses up to 300 mg/kg/day.

Mutagenesis: Eszopiclone was positive in the mouse lymphoma chromosomal aberration assay and produced an equivocal response in the Chinese hamster ovary cell chromosomal aberration assay. It was not mutagenic or clastogenic in the bacterial Ames gene mutation assay, in an unscheduled DNA synthesis assay, or in an *in vivo* mouse bone marrow micronucleus assay.

(S)-N-desmethyl zopiclone, a metabolite of eszopiclone, was positive in the Chinese hamster ovary cell and human lymphocyte chromosomal aberration assays. It was negative in the bacterial Ames mutation assay, in an *in vitro* ^{32}P-postlabeling DNA adduct assay, and in an *in vivo* mouse bone marrow chromosomal aberration and micronucleus assay.

Impairment Of Fertility: Eszopiclone was given by oral gavage to male rats at doses up to 45 mg/kg/day from 4 weeks premating through mating and to female rats at doses up to 180 mg/kg/day from 2 weeks premating through day 7 of pregnancy. An additional study was performed in which only females were treated, up to 180 mg/kg/day. Eszopiclone decreased fertility, probably because of effects in both males and females, with no females becoming pregnant when both males and females were treated with the highest dose; the no-effect dose in both sexes was 5 mg/kg (16 times the MRHD on a mg/m^2 basis). Other effects included increased preimplantation loss (no-effect dose 25 mg/kg), abnormal estrus cycles (no-effect dose 25 mg/kg), and decreases in sperm number and motility and increases in morphologically abnormal sperm (no-effect dose 5 mg/kg).

Pregnancy

Pregnancy Category C: Eszopiclone administered by oral gavage to pregnant rats and rabbits during the period of organogenesis showed no evidence of teratogenicity up to the highest doses tested (250 and 16 mg/kg/day in rats and rabbits, respectively; these doses are 800 and 100 times, respectively, the maximum recommended human dose [MRHD] on a mg/m^2 basis). In the rat, slight reductions in fetal weight and evidence of developmental delay were seen at maternally toxic doses of 125 and 150 mg/kg/day, but not at 62.5 mg/kg/day (200 times the MRHD on a mg/m^2 basis).

Eszopiclone was also administered by oral gavage to pregnant rats throughout the pregnancy and lactation periods at doses of up to 180 mg/kg/day. Increased postimplantation loss, decreased postnatal pup weights and survival, and increased pup startle response were seen at all doses; the lowest dose tested, 60 mg/kg/day, is 200 times the MRHD on a mg/m^2 basis. These doses did not produce significant maternal toxicity. Eszopiclone had no effects on other behavioral measures or reproductive function in the offspring.

There are no adequate and well-controlled studies of eszopiclone in pregnant women. Eszopiclone should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Labor And Delivery: LUNESTA has no established use in labor and delivery.

Nursing Mothers: It is not known whether LUNESTA is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when LUNESTA is administered to a nursing woman.

Pediatric Use: Safety and effectiveness of eszopiclone in children below the age of 18 have not been established.

Geriatric Use: A total of 287 subjects in double-blind, parallel-group, placebo-controlled clinical trials who received eszopiclone were 65 to 86 years of age. The overall pattern of adverse events for elderly subjects (median age = 71 years) in 2-week studies with nighttime dosing of 2 mg eszopiclone was not different from that seen in younger adults. LUNESTA 2 mg exhibited significant reduction in sleep latency and improvement in sleep maintenance in the elderly population.

ADVERSE REACTIONS

The premarketing development program for LUNESTA included eszopiclone exposures in patients and/or normal subjects from two different groups of studies: approximately 400 normal subjects in clinical pharmacology/pharmacokinetic studies, and approximately 1550 patients in placebo-controlled clinical effectiveness studies, corresponding to approximately 263 patient-exposure years. The conditions and duration of treatment with LUNESTA varied greatly and included (in overlapping categories) open-label and double-blind phases of studies, inpatients and outpatients, and short-term and longer-term exposure. Adverse reactions were assessed by collecting adverse events, results of physical examinations, vital signs, weights, laboratory analyses, and ECGs.

Adverse events during exposure were obtained primarily by general inquiry and recorded by clinical investigators using terminology of their own choosing. Consequently, it is not possible to provide a meaningful estimate of the proportion of individuals experiencing adverse events without first grouping similar types of events into a smaller number of standardized event categories. In the tabulations that follow, COSTART terminology has been used to classify reported adverse events.

The stated frequencies of adverse events represent the proportion of individuals who experienced, at least once, a treatment-emergent adverse event of the type listed. An event was considered treatment-emergent if it occurred for the first time or worsened while the patient was receiving therapy following baseline evaluation.

Adverse Findings Observed in Placebo-Controlled Trials

Adverse Events Resulting in Discontinuation of Treatment: In placebo-controlled, parallel-group clinical trials in the elderly, 3.8% of 208 patients who received placebo, 2.3% of 215 patients who received 2 mg LUNESTA, and 1.4% of 72 patients who received 1 mg LUNESTA discontinued treatment due to an adverse event. In the 6-week parallel-group study in adults, no patients in the 3 mg arm discontinued because of an adverse event. In the long-term 6-month study in adult insomnia patients, 7.2% of 195 patients who received placebo and 12.8% of 593 patients who received 3 mg LUNESTA discontinued due to an adverse event. No event that resulted in discontinuation occurred at a rate of greater than 2%.

Adverse Events Observed at an Incidence of ≥2% in Controlled Trials. The following lists the incidence (% placebo, 2 mg, 3 mg, respectively) of treatment-emergent adverse events from a Phase 3 placebo-controlled study of LUNESTA at doses of 2 or 3 mg in non-elderly adults. Treatment duration in this trial was 44 days. Data are limited to adverse events that occurred in 2% or more of patients treated with LUNESTA 2 mg (n=104) or 3 mg (n=105) in which the incidence in patients treated with LUNESTA was greater than the incidence in placebo-treated patients (n=99).[1]

Body as a whole: headache (13%, 21%, 17%), viral infection (1%, 3%, 3%). Digestive system: dry mouth (3%, 5%, 7%), dyspepsia (4%, 4%, 5%), nausea (4%, 5%, 4%), vomiting (1%, 3%, 0%). Nervous system: anxiety (0%, 3%, 1%), confusion (0%, 0%, 3%), depression (0%, 4%, 1%), dizziness (4%, 5%, 7%), hallucinations (0%, 1%, 3%), libido decreased (0%, 0%, 3%), nervousness (3%, 5%, 0%), somnolence (3%, 10%, 8%). Respiratory system: infection (3%, 5%, 10%). Skin and appendages: rash (1%, 3%, 4%). Special senses: unpleasant taste (3%, 17%, 34%). Urogenital system: dysmenorrhea* (0%, 3%, 0%), gynecomastia** (0%, 3%, 0%).

*Gender-specific adverse event in females

**Gender-specific adverse event in males

[1]Events for which the LUNESTA incidence was equal to or less than placebo are not listed, but included the following: abnormal dreams, accidental injury, back pain, diarrhea, flu syndrome, myalgia, pain, pharyngitis, and rhinitis.

Adverse events that suggest a dose-response relationship in adults include viral infection, dry mouth, dizziness, hallucinations, infection, rash, and unpleasant taste, with this relationship clearest for unpleasant taste.

The following lists the incidence (% placebo, 2 mg, 3 mg, respectively) of treatment-emergent adverse events from combined Phase 3 placebo-controlled studies of LUNESTA at doses of 1 or 2 mg in elderly adults (ages 65-86). Treatment duration in these trials was 14 days. Data are limited to events that occurred in 2% or more of patients treated with LUNESTA 1 mg (n=72) or 2 mg (n=215) in which the incidence in patients treated with LUNESTA was greater than the incidence in placebo-treated patients.[1]

Body as a whole: accidental injury (1%, 0%, 3%), headache (14%, 15%, 13%), pain (2%, 4%, 5%). Digestive system: diarrhea (2%, 4%, 2%), dry mouth (2%, 3%, 7%), dyspepsia (2%, 6%, 2%). Nervous system: abnormal dreams (0%, 3%, 1%), dizziness (2%, 1%, 6%), nervousness (1%, 0%, 2%), neuralgia (0%, 3%, 0%). Skin and appendages: pruritus: (1%, 4%, 1%). Special senses: unpleasant taste (0%, 8%, 12%). Urogenital system: urinary tract infection (0%, 3%, 0%).

[1]Events for which the LUNESTA incidence was equal to or less than placebo are not listed, but included the following: abdominal pain, asthenia, nausea, rash, and somnolence.

Adverse events that suggest a dose-response relationship in elderly adults include pain, dry mouth, and unpleasant taste, with this relationship again clearest for unpleasant taste. These figures cannot be used to predict the incidence of adverse events in the course of usual medical practice because patient characteristics and other factors may differ from those that prevailed in the clinical trials. Similarly, the cited frequencies cannot be compared with figures obtained from other clinical investigations involving different treatments, uses, and investigators.

The cited figures, however, do provide the prescribing physician with some basis for estimating the relative contributions of drug and non-drug factors to the adverse event incidence rate in the population studied.

Other Events Observed During The Premarketing Evaluation Of LUNESTA. Following is a list of modified COSTART terms that reflect treatment-emergent adverse events as defined in the introduction to the **ADVERSE REACTIONS** section and reported by approximately 1550 subjects treated with LUNESTA at doses in the range of 1 to 3.5 mg/day during Phase 2 and 3 clinical trials throughout the United States and Canada. All reported events are included except those already listed here or listed elsewhere in labeling, minor events common in the general population, and events unlikely to be drug-related. Although the events reported occurred during treatment with LUNESTA, they were not necessarily caused by it.

Events are listed in order of decreasing frequency according to the following definitions: **frequent** adverse events are those that occurred on one or more occasions in at least 1/100 patients; **infrequent** adverse events are those that occurred in fewer than 1/100 patients but in at least 1/1,000 patients; **rare** adverse events are those that occurred in fewer than 1/1,000 patients. Gender-specific events are categorized based on their incidence for the appropriate gender.

Frequent: chest pain, migraine, peripheral edema.

Infrequent: acne, agitation, allergic reaction, alopecia, amenorrhea, anemia, anorexia, apathy, arthritis, asthma, ataxia, breast engorgement, breast enlargement, breast neoplasm, breast pain, bronchitis, bursitis, cellulitis, cholelithiasis, conjunctivitis, contact dermatitis, cystitis, dry eyes, dry skin, dyspnea, dysuria, eczema, ear pain, emotional lability, epistaxis, face edema, female lactation, fever, halitosis, heat stroke, hematuria, hernia, hiccup, hostility, hypercholesteremia, hypertension, hypertonia, hypesthesia, incoordination, increased appetite, insomnia, joint disorder (mainly swelling, stiffness, and pain), kidney calculus, kidney pain, laryngitis, leg cramps, lymphadenopathy, malaise, mastitis, melena, memory impairment, menorrhagia, metrorrhagia, mouth ulceration, myasthenia, neck rigidity, neurosis, nystagmus, otitis externa, otitis media, paresthesia, photosensitivity, reflexes decreased, skin discoloration, sweating, thinking abnormal (mainly difficulty concentrating), thirst, tinnitus, twitching, ulcerative stomatitis, urinary frequency, urinary incontinence, urticaria, uterine hemorrhage, vaginal hemorrhage, vaginitis, vertigo, vestibular disorder, weight gain, weight loss.

Rare: abnormal gait, arthrosis, colitis, dehydration, dysphagia, erythema multiforme, euphoria, furunculosis, gastritis, gout, hepatitis, hepatomegaly, herpes zoster, hirsutism, hyperacusis, hyperesthesia, hyperlipemia, hypokalemia, hypokinesia, iritis, liver damage, maculopapular rash, mydriasis, myopathy, neuritis, neuropathy, oliguria, photophobia, ptosis, pyelonephritis, rectal hemorrhage, stomach ulcer, stomatitis, stupor, thrombophlebitis, tongue edema, tremor, urethritis, vesiculobullous rash.

DRUG ABUSE AND DEPENDENCE

Controlled Substance Class: LUNESTA is a Schedule IV controlled substance under the Controlled Substances Act. Other substances under the same classification are benzodiazepines and the nonbenzodiazepine hypnotics zaleplon and zolpidem. While eszopiclone is a hypnotic agent with a chemical structure unrelated to benzodiazepines, it shares some of the pharmacologic properties of the benzodiazepines.

Abuse, Dependence, and Tolerance

Abuse and Dependence: In a study of abuse liability conducted in individuals with known histories of benzodiazepine abuse, eszopiclone at doses of 6 and 12 mg produced euphoric effects similar to those of diazepam 20 mg. In this study, at doses 2-fold or greater than the maximum recommended doses, a dose-related increase in reports of amnesia and hallucinations was observed for both LUNESTA and diazepam.

The clinical trial experience with LUNESTA revealed no evidence of a serious withdrawal syndrome. Nevertheless, the following adverse events included in DSM-IV criteria for uncomplicated sedative/hypnotic withdrawal were reported during clinical trials following placebo substitution occurring within 48 hours following the last LUNESTA treatment: anxiety, abnormal dreams, nausea, and upset stomach. These reported adverse events occurred at an incidence of 2% or less. Use of benzodiazepines and similar agents may lead to physical and psychological dependence. The risk of abuse and dependence increases with the dose and duration of treatment and concomitant use of other psychoactive drugs. The risk is also greater for patients who have a history of alcohol or drug abuse or history of psychiatric disorders. These patients should be under careful surveillance when receiving LUNESTA or any other hypnotic.

Tolerance: Some loss of efficacy to the hypnotic effect of benzodiazepines and benzodiazepine-like agents may develop after repeated use of these drugs for a few weeks.

No development of tolerance to any parameter of sleep measurement was observed over six months. Tolerance to the efficacy of LUNESTA 3 mg was assessed by 4-week objective and 6-week subjective measurements of time to sleep onset and sleep maintenance for LUNESTA in a placebo-controlled 44-day study, and by subjective assessments of time to sleep onset and WASO in a placebo-controlled study for 6 months.

OVERDOSAGE

There is limited premarketing clinical experience with the effects of an overdosage of LUNESTA. In clinical trials with eszopiclone, one case of overdose with up to 36 mg of eszopiclone was reported in which the subject fully recovered. Individuals have fully recovered from racemic zopiclone overdoses up to 340 mg (56 times the maximum recommended dose of eszopiclone).

Signs And Symptoms: Signs and symptoms of overdose effects of CNS depressants can be expected to present as exaggerations of the pharmacological effects noted in preclinical testing. Impairment of consciousness ranging from somnolence to coma has been described. Rare individual instances of fatal outcomes following overdose with racemic zopiclone have been reported in European postmarketing reports, most often associated with overdose with other CNS-depressant agents.

Recommended Treatment: General symptomatic and supportive measures should be used along with immediate gastric lavage where appropriate. Intravenous fluids should be administered as needed. Flumazenil may be useful. As in all cases of drug overdose, respiration, pulse, blood pressure, and other appropriate signs should be monitored and general supportive measures employed. Hypotension and CNS depression should be monitored and treated by appropriate medical intervention. The value of dialysis in the treatment of overdosage has not been determined.

Poison Control Center: As with the management of all overdosage, the possibility of multiple drug ingestion should be considered. The physician may wish to consider contacting a poison control center for up-to-date information on the management of hypnotic drug product overdosage.

Rx only.

SEPRACOR 12/06

The patient who comes in for a checkup may have competing worries and anxieties—perhaps a family history of cancer, heart palpitations, or symptoms of diabetes. Including a crash course in "Disaster Preparedness" in the office visit may bring on more angst and leave less time for the matter at hand. But emergency preparedness education can be as simple as providing a collection of CDC brochures in a waiting room.

"Be an advocate," says David Markenson, MD, FAAP, EMT-P, Chair, American Red Cross Advisory Council on First Aid and Safety in New York, NY. "If the doctor tells [a patient] to think about emergency preparedness and family preparedness, most patients will respect their credibility." At the very least, physicians should inform patients what to do if they need a prescription or medical care during a widespread emergency.

HMOs or prescription plans may not pay for extra months of medication; so many patients may not have extra medications on hand. In the days immediately after Hurricane Katrina, patients had trouble replacing their medications because they didn't know how to contact their providers.

There was similar confusion in Port Charlotte, Fla., after Hurricane Charley hit the area. Terence P. Connelly, MD, a cardiologist at the Charlotte Heart and Vascular Institute in Port Charlotte, lost his home and his office building. After the storm, Dr. Connelly ran a clinic outside his damaged office. People showed up for prescriptions and other medical supplies because local pharmacies were closed. Replacing those prescriptions turned out to be his most useful service: "In a disaster, we don't need to be doing heart catheters," says Dr. Connelly. "What turned out to be the most useful thing for us to have right after the hurricane was drug samples."

Preparing Yourself and Your Staff

Paul Biddinger, MD, Chairman of the Massachusetts Medical Society Committee on Preparedness, strongly believes that physicians have a great opportunity to talk about the significant disasters, both natural and manmade, that the country has seen in the past several years and the medical reasons for emergency preparedness. "Yes, we care about blood pressure, blood sugar, and cholesterol levels, but we also care about patients' ability to

care for themselves and their families. It's a good opportunity to make sure every family has an emergency preparedness plan and kit at home," says Dr. Biddinger. Physicians can refer patients to the Federal government's preparedness Website, *www.ready.gov*, and should remind patients of the importance of a family communication plan, because one of the greatest challenges in disasters is finding loved ones.

Another way to subtly remind patients about emergency preparedness is to post basic information on the practice's Website on how to reach the practice in case of an unexpected emergency. This is the tactic used by the American Academy of Pedi-

Hurricane Hero

Mark O. Asperilla, MD, FACP, found an intense need for prescription drugs in the Port Charlotte area after the hurricane. He had been instrumental in the founding of a non-profit pharmacy in the community several years before. After Charley hit, the St. Vincent de Paul pharmacy was one of the first back in operation. With the help of six volunteer doctors, the pharmacy began filling emergency prescriptions and even became a makeshift distribution center before FEMA came in. Dr. Asperilla arranged for an emergency radio broadcast to direct people who needed medications to the pharmacy.

But Dr. Asperilla didn't stop there in his response to the emergency in his community. After setting up the emergency prescription service, Dr. Asperilla approached FEMA in the hopes of opening a clinic among the community of FEMA trailers for people who had lost their homes. When he met some initial hesitation at FEMA, he turned to his congressman for help. The first FEMA clinic was born.

As the community began to recover physically, Dr. Asperilla saw a need for counseling to address a rising incidence of drug and alcohol abuse and domestic violence among those displaced by the storm. Representatives of the Substance Abuse and Mental Health Services Administration worked with FEMA and the Florida Department of Children and Families to offer crisis counseling and a toll-free information and referral hotline. The FEMA clinic that Dr. Asperilla helped launch is now the same template model that is being used in Louisiana in the wake of Katrina.

For his efforts, Dr. Asperilla received the Point of Light Award from the state of Florida and was dubbed a "Hurricane Hero" by Governor Jeb Bush.

atrics Task Force on Terrorism, which was launched after September 11. "Since it's hard for a busy practicing physician to spend a significant amount of time with each patient helping them prepare for a disaster, the approach of the American Academy of Pediatrics has been to have information available so that when a disaster is imminent (or in process), the physician treating children will have a resource for credible current information that is useful and can be disseminated to families," says Carden Johnston, MD, FAAP, FRCP (London), and member of the AAP Task Force on Terrorism. The Website is *http://www.aap.org/terrorism/topics/disaster_planning.html*.

Although patients increasingly look to the Internet for health information, they often turn to their doctors to help them sift through the information. In an emergency situation, staff may have to deal with a surge of phone calls and walk-in patients with questions.

It's important to prepare staff for common questions and problems that will come up during an emergency situation. "In a disaster the most likely calls a doctor's office is going to receive are

Get Your Masks Now

The N95, or higher-filtering face-piece respirator, approved by the National Institute for Occupational Safety and Health, is designed to protect people from breathing in very small particles, which might contain viruses. The N95—which covers the mouth and nose, and sometimes has small valves in front to facilitate breathing in and out—is constructed of heavy fibers that can block even tiny particles. In the event of a pandemic, the Centers for Disease Control recommends that well people wear an N95 respirator whenever they are within six feet of sick people.

The Power Air-purifying respirator is an expensive piece of equipment—around $200—that has a rubber hose that drops to the waist, along with a battery pack. If the infectious disease can be spread through droplets, safety goggles can be worn to protect from infection, suggests Robyn R. Gershon, MHS, Dr. Ph. Professor of Clinical Sociomedical Sciences at Columbia University Mailman School of Public Health.

During an emergency, N95 masks will be in short supply. Dr. Ger-

these: I don't have my medicine; my appointment at the hospital has been canceled; I don't have the medical equipment I need. The doctor's plan should include who is going to handle those phone calls and what resources the doctor will be able to provide his patients," says Dr. Markenson.

Many of these questions will require answers specific to the area of practice. However, bookmarking a few key Websites may also help staff respond to more general questions. Key sites to mark are the following:

- The Centers for Disease Control (*www.cdc.gov*)
- The National Institutes of Health (*www.nih.gov*)
- MedlinePlus (*www.medlineplus.gov*)
- Specialty Websites
- Patient advocacy organizations

For example, the CDC Website has a variety of downloadable patient education flyers and brochures, as well as up-to-date links to valuable emergency preparedness resources. "There is an incredible amount of material on the site, which is updated regularly," says Michael R. Grey, MD, MPH, professor of med-

shon recommends stocking up now and making sure staff are properly fitted with the equipment. N95 masks need to be fit tested, and the vendor or brand manufacturer may send a consultant to the facility for this purpose. Men with beards and people with thin faces will have problems wearing the masks.

"Most of the leakage with N95 respirators occurs around the edges where the respirator meets the face. If someone doesn't have the appropriate-size respirator, he or she will not have the needed protection," says Anita Barry, MD, Director of Communicable Disease Control for Boston Public Health Commission.

For more Information on mask and respirator selection, consult the following Websites:

- *www.osha.gov/SLTC/etools/respiratory/oshafiles/fittesting1.html*
- *www.osha.gov/SLTC/etools/respiratory/advisor_genius_nrdl/advisor_genius.html*
- *www.fda.gov/cdrh/ppe/masksrespirators.html#1*
- *www.hospitalinfection.org/innovative.shtml*
- *www.cdc.gov/od/oc/media/pressrel/2007/r070503.htm*

icine at Tufts University School of Medicine and co-author of *The Bioterrorism Sourcebook* (McGraw-Hill Medical Publishing Division, 2006). Doctors can research anything from avian flu to spotted fever.

While online sources are often the most up-to-date, Dr. Grey recommends keeping an emergency preparedness library of books and printouts on hand as well. "Right after the anthrax attacks in New York in 2001, the CDC Website crashed because it couldn't handle the volume of all the people trying to get information," Dr. Grey points out. With hard copies of reliable sources at their fingertips, physicians and their staff won't get frustrated by an overwhelmed Website.

The CDC's Clinician Information Service was created specifically as a way to communicate information about disease outbreaks and terrorism alerts to physicians nationwide. Doctors who join the list serve can listen in on conference calls on different news relating to topics from anthrax and avian flu to viral hemorrhagic fevers and West Nile disease.

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"I would encourage not only physicians but anybody who participates in some form of health care—clinicians, nurses, physician assistants—to be on this list serve because it's a really valuable resource," says Rossanne M. Philen, MD, Medical Director for the Epidemic Information Exchange, (*EPI-X*) for the CDC.

According to Tener Veenema, MD, associate professor of nursing at Rochester University, New York, and author of *Disaster Nursing and Emergency Preparedness for Chemical, Biological, and Radiological Terrorism* (April 2007, Springer Publishing), nursing staff will need special training because of their special role on the staff of a medical practice. Dr. Veenema

explains that since the 1950s, when infectious diseases were contained with penicillin and the advent of broad-spectrum antibiotics, nursing education has shifted to acute care or critical care medicine. Although many recognize the need for more disaster planning education, the course offerings may be scant. "Schools of nursing have been very slow to adopt disaster content into their curriculum because the curriculum is already jam packed," says Dr. Veenema. "In an era of nursing shortages and condensed accelerated nursing programs, it becomes a real challenge to add more content to these courses."

Some of the training recommended for effective disaster response is also good preparation for everyday emergencies. Dr. Markenson recommends that *all* office staff—including administrators, receptionists, and other non-clinical staff—be trained in basic first aid and CPR. Physicians should also consider cross-training nurses to be familiar with administrative tasks, such as scheduling.

"We recommend the 1-2-3 approach," Dr. Markenson explains. "For every one person in an organization, two other people are trained to do what they do." This helps prepare the staff to continue with essential functions even in the midst of severe staff shortages.

Creating a staffing contingency plan should be part of a physician's emergency plan. By contacting prospective emergency staff before an unexpected event, physicians know whom they can call if they need "surge capacity."

"One idea is to call retirees who worked for the practice in the past, and ask them if they would be willing to work again should the practice need extra staff," suggests Robyn R. M. Gershon, MHS, DrP, Professor of Clinical Sociomedical Sciences at Columbia University Mailman School of Public Health. Dr. Gershon has found in her research that older people were more willing to work during public health crises than people under age 45.

Joining forces with another physician's office is another way to help ensure that an office would not be understaffed during an emergency. For example, a physician might arrange for a "floating staff" to work half the day at one practice and in the afternoon switch to the other practice.

"None of this is rocket science," admits Suzanne Rhulen

Loughlin, Esq., Executive Vice President/Chief Administrative Officer for Firestorm Solutions. "What we're talking about here are common-sense ways to prepare." She points out that while you might not know what will happen or when, it's fairly clear that a physician's practice will eventually face some sort of emergency situation. "Maybe not a pandemic, this year or next year, but someday there will be [an emergency]," she says.

Counting on Staff

Firestorm Solutions recommends that early in the process, businesses involve employees in the development of a plan, and perform test drills so that emergency preparedness simply becomes integrated into part of the culture. By including employees in the planning, physicians can get an idea of which staff members would have other pressing concerns and whom they can count on to work during an emergency. It also gives

Infection Control at the Office

Practice waiting rooms are a perfect place to spread infection. Well patients and family members are crowded together in a windowless room, sharing magazines with sick patients who are coughing and sneezing. Although solutions may be limited by the practice's space, there are often simple measures staff can take to fine-tune respiratory hygiene and other infection control measures.

In a University of Ottawa research study published in *Canada Family Physician* (October 2006) researchers monitored patient response and reaction to new waiting room hygiene guidelines. Signs promoting good respiratory hygiene were displayed in the waiting room and patients were offered a mask if they had a fever or a cough. Staff instructed patients to clean their hands with alcohol gel and sit at least one meter apart from each other. The study uncovered that annual cost per physician to keep this hygiene monitoring running would be $800 per physician. Although seeing a nurse wearing a mask in a doctor's waiting room is an uncommon sight, the study found that most patients were cooperative and open to the new rules in place to protect everyone's health.

In order to put in place stricter measures, all intake people in a medical practice must be briefed and on board. Robin B. McFee, DO, MPH, toxicologist and professional training coordinator at the Long

staff a chance to address any fears they may have about their own safety during an emergency and to gain some familiarity with the level of preparedness of the office.

In a study ("Healthcare Workers' Ability and Willingness to Report to Duty During Catastrophic Disasters," *Journal of Urban Health*, September, 2005), researchers surveyed over 6,000 healthcare workers from 47 different New York healthcare facilities and analyzed willingness to respond versus ability to respond. The scenarios that health workers were least willing to respond to were a smallpox epidemic (61%), a radiological event (57%), or a SARS outbreak (48%). The hypothetical health emergencies that people were most willing to report to were a mass casualty incident (86%) and an environmental disaster (84%).

Dr. Gershon, who led the study, says that the unwillingness of healthcare workers to report to certain public health crises is based on the "What can this do to me?" factor. She cites Peter

Island (New York) Regional Poison and Drug Information Center, offers these strategies for respiratory hygiene:

- Encourage staff to take more aggressive precautions, perhaps offering a coughing patient a mask,
- Keep hand-cleaning gels available around the office and in the waiting room,
- Set up to a system by which potentially contagious patients (for example, those with a fever and a rash) can be whisked into a special exam room as quickly as possible.

Anita Barry, MD, Director of Communicable Disease Control for Boston Public Health Commission, says for an airborne infection, such as measles, the most desired setting is in an airborne infection isolation room, which is a room that is under negative pressure and has a certain number of air exchanges an hour. However, most physician offices don't have these. In that case she recommends the next best thing: a private room with the door closed.

"You have a window in a room to open to air a room out after a patient has been there. Make sure people who are going into that room wear the appropriate personal protective gear," says Dr. Barry.

Note: The CDC has a "Cover Your Cough" poster/flyer that can be downloaded at *www.cdc.gov/flu/protect/covercough.htm*.

Sandman, PhD, a risk communications consultant based in Princeton, NJ, and the creator of the "Risk = Hazard + Outrage" formula. Dr. Sandman has written extensively on what he calls the "the dread factor," associated with rare ailments that have no treatment and no cure. For example, the high fatality rate among those who contract avian flu inspires a high level of dread. People fear radiation because it is invisible.

The unknown also inspires dread; smallpox is so rare that most healthcare professionals have little experience with it. At the time of the SARS outbreak, doctors and health officials

What's wrong with this picture?

Each of these situations contains a serious infraction of infection-control procedures. Can your staff identify the problem?

- You greet your kids with hugs when you arrive home from a shift at the hospital. Before you settle in to hear about their days, you take off your lab coat.
  What's wrong? *Your clothing is a vector for disease; take the time to change your clothes before leaving work. This includes shoes, which can track bacteria all the way to your carpet at home. For example, if you treated a person with MRSA (methicillin-resistant* staphylococcus aureus*) or a patient colonized with MRSA, 65 percent of the time, your clothing will be contaminated.*
- You make sure you wear a fresh new lab coat every day.
  What's wrong? *You should wear a clear plastic or disposable paper gown over your lab coat.*
- To amuse two young brothers who are being examined at the same time, you check their heartbeats one after the other.
  What's wrong? *You should clean stethoscopes between patients.*
- For emotional support, your sick patient brings his best friend in to keep him company. You allow them to walk around the hallways to kill time.
  What's wrong? *Sick patients should not walk around the hospital. Visitors should wear protective gear. In Toronto, relatives came to visit a SARS patient, then went to the cafeteria and in the elevator. In the process, they spread the disease to other people.*
- You don a paper gown before intubating a patient.
  What's wrong? *When you're intubating a patient, you should also wear an N-95 mask to prevent contamination from mucous.*

didn't know what the routes into the body were. This increased fear as healthcare professionals weren't sure they were being adequately protected with the equipment given to them. "They knew the disease had a high fatality rate and infection rate, and they knew of healthcare workers who were getting sick and dying," says Dr. Gershon.

But perhaps the aspect that scares healthcare workers most is the chance that they may spread contagion to their family members and loved ones.

It's not surprising that this fear would be a deal breaker among healthcare workers. Even though the physicians who were surveyed were the most likely to respond to all types of events, they too voiced concern about endangering their families. If quarantine were called for, many nurses and workers worried about who would take care of their families, pets, etc.

What scares healthcare workers most is the chance that they may spread contagion to their family members and loved ones. Even though the physicians who were surveyed were the most likely to respond to all types of events, they too voiced concern about endangering their families. If quarantine were called for, many nurses and workers worried about who would take care of their families, pets, etc.

Knowing staff members' particular fears and responsibilities in the event of disaster is key to preparedness. Dr. Gershon says it's critical to have the "Are you willing?" dialogue *before* the moment of urgency arrives.

One way to boost employee confidence in a practice's disaster plan is to reassure staff ahead of time that a pandemic plan is in place and that proper protective equipment is ready to go. Talking about staff and physician protection is one of the first steps in opening the "willingness" dialogue.

"A physician should assure staff that N95 respirator facemasks will be available so that when patients come in and they're not sure if it's the regular flu or the bird flu, they will have the mask for protection," says Dr. Gershon.

A tabletop talk-through, discussing each staff member's own family emergency plans, can give doctors a realistic expectation as to who will be able to work and who will have to be home, no matter what happens. Questions a physician can ask staff include the following:

- What will we do if 30 to 40 percent of staff members are sick or unable to work?
- Under what circumstances should the practice close?
- What types of family emergency plan do staff members have?

Staff Preparedness

One way to help protect staff and patients from new contagions is to ensure that everyone is up to date with vaccinations—including healthy adults. During the measles outbreak in Boston in 2006, the Boston Health Commission uncovered that a cohort of people in the United States had received an ineffective measles vaccination between 1963 and January 1968. "We were finding people who were born 1957 or later who had had their childhood vaccinations, but were susceptible to measles," says Dr. Barry. Healthcare workers who couldn't prove immunity to measles were instructed not to come to work.

Physicians should survey staff and patients to see who might need a pneumonia or pneumococcal vaccine. This vaccine is an essential piece of protection because the bacterial infection superimposed on influenza complicates the illness and raises the risk of death. A pneumococcal vaccine, explains Dr. Barry, may prevent that complication.

The CDC also recommends influenza vaccine for all healthcare workers as well as many patients, including adults who are in close contact with children five years old and under (especially infants who are too young to get the vaccine), adults and children with certain medical conditions, pregnant women, and people 65 years old and older.

"Currently about 73% of the U.S. population is in a group targeted for vaccination. Among healthy working adults, the vaccine has been shown to decrease illness, work absenteeism, and antibiotic use," says Carolyn Bridges, MD, Associate Director for Science for the CDC.

In the event of a pandemic flu, prolonged worker absenteeism could reach all-time highs, contributing to a major economic recession. A new report released in March 2007 by The Trust for America's Health predicts that a severe flu pandemic could lead to a major economic recession, possibly the second worst recession in the U.S. since World War II. The Trust for America's

Health projects that there could be 2.25 million fatalities in the U.S. alone, and 87.75 million might miss work due to illness or caring for sick people. Every disaster leads to some type of financial hardship, according to Suzanne Loughlin, Chief Administrative Officer of Firestorm Solutions, a risk management consulting firm in Golden, Colo. In Hurricane Katrina's aftermath, the unemployment system failed to help people who lost their jobs overnight because their employers had been wiped out. After seeing the lessons learned from Katrina, certain states are modifying their entire systems.

Practices that haven't yet switched to direct deposit of employee's paychecks may choose to consider it. This system would be very helpful during a pandemic as people will wish to avoid human contact as much as possible. Direct deposit may also facilitate unemployment payments if such arrangements should become necessary, says Ms. Loughlin.

Practices that haven't yet switched to direct deposit of employee's paychecks may choose to consider it. This system would be very helpful during a pandemic as people will wish to avoid human contact as much as possible. Employees will not want to go to their local banks to deposit a paycheck, even if some banks remain open. Direct deposit may also facilitate unemployment payments if such arrangements should become necessary, says Ms. Loughlin.

One of the legal questions that has yet to be answered is this: "If an employee comes to work, and a co-worker turns out to be ill, and the first employee contracts avian flu, is it a Worker's Compensation claim?"

Benefits are another hot-button issue for doctors in the event of a pandemic because many staff members may request sick leave, vacation pay, or unemployment compensation at the same time the physician is paying for temporary help to keep the practice going.

Drills 101

Once an emergency plan is in place, a physician can test it by having a drill with staff. People may think of emergency drills as a disruption from the day's work. But the fact is, drills work.

When the alarm does go off, staff members know what to do. And the good news is that preparation for one type of emergency strengthens the staff response even if the emergency that arises is quite different from the drill.

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

Performing a tabletop drill with staff is a good launching pad for a planned drill. During the first run, an in-house-only group works through what triggers the event, explains Mr. Satterfield. He says the following key issues should be addressed:

- Do employees have adequate child care arrangements for their families?
- How should the practice notify staff and patients of any emergency situation?
- How does the practice communicate with local authorities?
- What methods of crowd control will staff use?

Lessons From Toronto

The newly released SARS Commission report, published by the government of Ontario, provides a sobering account of what hospitals in Ontario failed to do to prevent the transmission of SARS. Here are lessons learned from that experience:

- Rigorous infection prevention practiced day after day is the best preparation for the arrival of an unknown pathogen.
- In the event of such an emergency, death toll depends largely on what hospitals do when the first patients are admitted. If hospitals have effective infection controls already in place, they can prevent an unknown disease from spreading to other patients or staff.
- Experts say most hospitals are woefully underprepared. Hospitals that fail to stop ordinary infections spread by touch only will not be able to contain viruses, which are communicated by droplets from coughing and sneezing as well as by touch. Even more challenging are diseases such as smallpox, plague, and other bioterrorism weapons that can travel through the air.
- Hospitals should have on hand supplies of N95 masks and should

- How will the practice separate sick patients and staff from healthy patients and staff?
- How will the practice acquire more supplies, if needed?
- How will prescription drug shortages be addressed?
- What happens to routine appointments?
- Are there any special considerations needed for handling billing and collections?
- What if a patient dies in the office?
- Will the practice use volunteers to augment staff? How will these volunteers be notified to come in?
- What will the practice do to contain disease and protect staff during the crisis?

Once a tabletop drill is worked out, a doctor can work on organizing a drill with "live" people by recruiting from the Red Cross, fire departments, patients, and even the media. There are also great opportunities to volunteer and be trained for "all hazards emergencies" through a local Medical Reserve Corps and the Red Cross. The American Medical Association offers National Disaster Life Support courses covering Basic Disaster

be sure that healthcare workers are properly fitted and trained to use them. Healthcare workers need both eye protection and N95 masks, particularly when intubating patients.

- Hospitals need to be aware that visitors (particularly relatives of patients already in the hospital) may be carrying disease. Hospitals should scrutinize visitation policies upon the arrival of a patient with an unknown disease.
- Patients with undiagnosed disease may arrive in the emergency room. ER workers should be alerted that highly contagious patients need to be identified and isolated quickly.
- Rigorous cleaning of hospital equipment is essential to stem the spread of pathogens easily spread by droplet or touch.
- Healthcare workers should be alerted on how to protect their own families and avoid bringing pathogens home on their clothing, uniforms, and shoes. Also, healthcare workers showing symptoms of disease should be advised how to protect their family members.

Source: Committee to Reduce Infection Deaths, www.hospitalinfection.org.

Life Support, Advanced Disaster Life Support, and Core Disaster Life Support for physicians, nurses, PAs, EMTs, allied health professionals, and medical students. For more information, course schedule, and locations across the country, go to *www.bdls.com*. The American College of Emergency Physicians also offers resources on disaster preparedness education (*www.acep.org)*.

Schedule the live drill shortly after people have reviewed their roles to ensure that things go smoothly. If the drill does not go well, schedule a second drill. The physician should feel comfortable that he or she and the staff are performing in an optimal way, advises Dr. Philen.

Once you've got the planned drill down, it's time to go ahead with an unplanned one. Don't rush into this, however; springing a surprise drill before everyone is familiar with the process can work against the confidence of the staff.

Dr. Philen says her division of the CDC performs drills regularly. "We do routine drills on an announced basis, but also on an unannounced basis. The feedback we've received is that the un-announced drills are very helpful to [staff members], but I wouldn't start with them," she says. "[Staff members] need to get a certain sense of accomplishment and familiarity with what they're doing before you pull an unplanned drill on them. Otherwise it's like a pop quiz. It helps to do the homework first."

Hygiene Refresher Course

"The best preparation for a pandemic, or for the arrival of an unknown disease, such as the avian flu, is rigorous infection control practiced every day in the hospital and physician's office," says Dr. Betsy McCaughey, former Lt. Governor of New York. Dr. McCaughey, founder of the Committee to Reduce Infection Deaths (*www.hospitalinfection.org*), cites the tale of two hospitals in Canada during the first outbreak of SARS. The story was documented in the SARS report that was released in January 2007. (For more information on the SARS report, visit *www.sarscommission.ca*.)

"Back in 2003, two middle-aged men with undiagnosed cases of SARS arrived at two hospitals, one in Vancouver, and the other one in Toronto, within hours of each other," Dr.

McCaughey recounts. "In Vancouver, where the hospital practiced rigorous infection control, this man was treated, and the disease did not spread to any other patient or visitor in the hospital. In Toronto, where procedures were lax and preparation was virtually nil, over 300 other people got the disease; and 77 percent of them contracted it in the hospital."

According to the Committee to Reduce Infection Rates, one out of 20 hospital patients acquires an infection during their stay. That translates to 2 million patients a year; of those, 103,000 die.

Dr. McCaughey explains that, because viruses are more difficult to contain than bacterial infections, a hospital that is unable to contain bacterial infections cannot expect to contain an unknown virus, which can be spread not only by touch, but also by droplets.

She maintains that rigorous hygiene is not about money or time, but about discipline and good training—down to the last detail. For example, she points to the doctors and nurses who carefully scrub and glove, then reach up to open the privacy curtain to see their next patient. "That curtain is virtually never changed," she says. "It is laden with bacteria, and the caregiver's hands are contaminated before they touch the patient. Although there is tremendous emphasis on hand hygiene, there is too much emphasis on cleaning your hands, and not enough attention on how to keep your hands from becoming re-contaminated before you reach the patient," she explains.

"Most hospitals and doctor's offices are woefully under-prepared for the arrival of an unknown pathogen, such as avian flu; and the best preparation is rigorous infection control practiced every day, and it will save lives whether these unknown diseases arrive here or not," says Dr. McCaughey.

"True preparedness means being as conclusive as possible," says Robin B. McFee, DO, MPH, toxicologist and professional training coordinator at the Long Island (New York) Regional Poison and Drug Information Center. "It really comes down to training, awareness, and practice. Even if you don't have a lot of N95 masks, and you don't have a lot of auto-injectors or medications, if you raise the alarm and get the right people in there at the right time, you've done your job."