

Study: Emergency On-Call Coverage Is Unraveling

BY KATE JOHNSON
Montreal Bureau

Emergency on-call coverage from specialist physicians is “unraveling” at hospitals across the country, resulting in delayed treatment, patient transfers, permanent injuries, and even death, according to a study from the Center for Studying Health System Change, a nonpartisan policy research group in Washington.

While the problem is predominantly an

issue for hospital emergency departments, it also is becoming increasingly problematic for inpatients who need urgent specialty care, according to the report. The findings are based on 2007 data from 12 nationally representative communities: Boston; Cleveland; Greenville, S.C.; Indianapolis; Lansing, Mich.; Little Rock, Ark.; Miami; Northern New Jersey; Orange County, Calif.; Phoenix; Seattle; and Syracuse, N.Y.

The picture is particularly grim given the fact that overall ED utilization rates have risen by 7% in the past decade, from 36.9 to 39.6 visits per 100 people, according to the report. While insured people account for the vast majority of ED visits, “the proportion of visits by uninsured people is rising at a relatively higher rate,” the study’s authors wrote.

Citing a 2006 paper from the American College of Emergency Physicians, the study reported that 73% of emergency departments in the United States report inadequate on-call coverage by specialist physicians. In particularly short supply are orthopedic surgeons, neurosurgeons, plastic surgeons, trauma surgeons, hand surgeons, obstetrician-gynecologists, neurologists, ophthalmologists, and dermatologists. While an actual shortage of such physicians may sometimes be to

blame, “physician unwillingness to take call appears to be a more pressing issue for many hospitals,” the study authors stated.

Although unwillingness to accept on-call duty is largely influenced by quality of life issues, the requirement to provide on-call coverage has traditionally been mandated by hospitals under the Emergency Medical Treatment and Labor Act. However, many specialists are now shifting their practices away from the hospital setting, and are no longer obligated by medical staff privileges, noted the report’s authors.

Many physicians also believe payment for on-call care is inadequate, especially when they are caring for uninsured patients. Specialists are also concerned that providing emergency care may increase their exposure to medical liability and drive up the cost of their malpractice premiums, according to the report.

As a result, adverse patient outcomes are reported. One study found that 21% of patient deaths or permanent injuries related to ED treatment delays are attributed to lack of specialists’ availability, noted the report. Complete lack of access to specialty care in some EDs is forcing either travel or transfer of patients. And for the physicians who continue to provide on-call coverage, increasing workload and decreasing

morale may put patients further at risk.

“It’s not a surprise that we’re having this problem—it’s a surprise to me that we have any on-call specialists at all,” Dr. Todd Taylor, previously an emergency physician and speaker for the ACEP Council, said in an interview. Dr. Taylor left clinical medicine last summer to work in the computer industry, he said, because the risks of liability were more than he could justify.

For Dr. Taylor, it is these very liability risks that are at the root of the current on-call crisis. “The liability issue has become the overriding barrier to physicians being willing to put themselves at risk,” he said.

More troubling than the lack of emergency on-call specialists, he added, is the lack of emergency physicians in general—a newer phenomenon reported earlier this year in the 2007 Daniel Stern & Associates Emergency Medicine Compensation and Benefits Survey.

“This has applied to on-call specialists for years, but the phenomenon is now spreading to core emergency physicians, who are increasingly seeking alternative careers,” Dr. Taylor said, noting that 30% of the study’s respondents said they were considering leaving medicine because of the malpractice climate. “That’s what’s different now compared to 2 or 3 years ago.” ■

LEXAPRO® (escitalopram oxalate) TABLETS/ORAL SOLUTION

(3% and <1%); Anorgasmia² (2% and <1%). *Events reported by at least 2% of patients treated with Lexapro are reported, except for the following events which had an incidence on placebo: Lexapro: headache, upper respiratory tract infection, back pain, pharyngitis, inflamed injury, anxiety. *Primarily ejaculatory delay. †Denominator used was for males only (N=225 Lexapro; N=188 placebo). ‡Denominator used was for females only (N=490 Lexapro; N=404 placebo). Generalized Anxiety Disorder Table 3 enumerates the incidence, rounded to the nearest percent of treatment-emergent adverse events that occurred among 429 GAD patients who received Lexapro 10 to 20 mg/day in placebo-controlled trials. Events included are those occurring in 2% or more of patients treated with Lexapro and for which the incidence in patients treated with Lexapro was greater than the incidence in placebo-treated patients. The most commonly observed adverse events in Lexapro patients (incidence of approximately 5% or greater and approximately twice the incidence in placebo patients) were nausea, ejaculation disorder (primarily ejaculatory delay), insomnia, fatigue, decreased libido, and anorgasmia (see TABLE 3). TABLE 3. Treatment-Emergent Adverse Events: Incidence in Placebo-Controlled Clinical Trials for Generalized Anxiety Disorder (Lexapro (N=429) and Placebo (N=427)).

Autonomic Nervous System Disorders: Dry Mouth (8% and 5%); Sweating Increased (4% and 1%).

Central & Peripheral Nervous System Disorders: Headache (24% and 17%); Paresthesia (2% and 1%); Indigestion (3% and 2%); Vomiting (3% and 1%); Abdominal Pain (2% and 1%); Flatulence (2% and 1%); Toothache (2% and 0%); General: Fatigue (8% and 2%); Influenza-like symptoms (5% and 4%); Musculoskeletal: Neck/Shoulder Pain (3% and 1%).

Psychiatric Disorders: Somnolence (13% and 7%); Insomnia (12% and 6%); Libido Decreased (7% and 2%); Dreaming Abnormal (3% and 2%); Appetite Decreased (3% and 1%); Lethargy (3% and 1%); Yawning (2% and 1%).

Urogenital: Ejaculation Disorder^{1,2} (14% and 2%); Anorgasmia² (6% and <1%); Menstrual Disorder (2% and 1%).

¹Events reported by at least 2% of patients treated with Lexapro are reported, except for the following events which had an incidence on placebo: Lexapro: inflamed injury, dizziness, back pain, upper respiratory tract infection, rhinitis, pharyngitis. †Denominator used was for males only (N=247 Lexapro; N=232 placebo). ‡Denominator used was for females only (N=490 Lexapro; N=404 placebo).

Dose Dependency of Adverse Events The potential dose dependency of common adverse events (defined as an incidence rate of ≥5% in either the 10 mg or 20 mg Lexapro groups) was examined on the basis of the combined incidence of adverse events in two fixed-dose trials. The overall incidence rates of adverse events in 10 mg Lexapro-treated patients (66%) was similar to that of the placebo-treated patients (61%), while the incidence rate in 20 mg Lexapro-treated patients was greater (86%). Table 4 shows common adverse events that occurred in the 20 mg/day Lexapro group with an incidence that was approximately twice that of the 10 mg/day Lexapro group and approximately twice that of the placebo group. TABLE 4. Incidence of Common Adverse Events* in Patients with Major Depressive Disorder Receiving Placebo (N=311), 10 mg/day Lexapro (N=310), 20 mg/day Lexapro (N=125): Insomnia (4%, 7%, 14%); Diarrhea (5%, 6%, 14%); Dry Mouth (3%, 4%, 9%); Somnolence (1%, 4%, 9%); Dizziness (2%, 4%, 7%); Sweating Increased (<1%, 3%, 8%); Constipation (1%, 3%, 6%); Fatigue (2%, 2%, 6%); Indigestion (1%, 2%, 6%).

Adverse events with an incidence rate of at least 5% in either of the Lexapro groups and with an incidence rate in the 20 mg/day Lexapro group that was approximately twice that of the 10 mg/day Lexapro group and the placebo group. Male and Female Sexual Dysfunction with SSRIs Although changes in sexual desire, sexual performance, and sexual satisfaction often occur as manifestations of a psychiatric disorder, they may also be a consequence of pharmacologic treatment. In particular, some evidence suggests that SSRIs can cause such untoward sexual experiences. Reliable estimates of the incidence and severity of untoward experiences involving sexual desire, performance, and satisfaction are difficult to obtain, however, in part because patients and physicians may be reluctant to discuss them. Accordingly, estimates of the incidence of untoward sexual experience and performance cited in product labeling are likely to underestimate their actual incidence. Table 5 shows the incidence rates of sexual side effects in patients with major depressive disorder and GAD in placebo-controlled trials. TABLE 5. Incidence of Sexual Side Effects in Placebo-Controlled Clinical Trials (In Males Only: Lexapro (N=407) and Placebo (N=383)); Ejaculation Disorder (primarily ejaculatory delay) (12% and 1%); Libido Decreased (6% and 2%); Impotence (2% and <1%). (In Females Only: Lexapro (N=737) and Placebo (N=636)); Libido Decreased (3% and 1%); Anorgasmia (3% and <1%). There are no adequately designed studies examining sexual dysfunction with escitalopram treatment. Praprim has been reported with all SSRIs. While it is difficult to know the precise risk of sexual dysfunction associated with the use of SSRIs, physicians should routinely inquire about such possible side effects. **Vital Sign Changes** Lexapro and placebo groups were compared with respect to (1) mean change from baseline in vital signs (pulse, systolic blood pressure, and diastolic blood pressure) and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. These analyses did not reveal any clinically important changes in vital signs associated with Lexapro treatment. In addition, a comparison of supine and standing vital sign measures in subjects receiving Lexapro indicated that Lexapro treatment is not associated with orthostatic changes. **Weight Changes** Patients treated with Lexapro in controlled trials did not differ from placebo-treated patients with regard to clinically important change in body weight. **Laboratory Changes** Lexapro and placebo groups were compared with respect to (1) mean change from baseline in various serum chemistry, hematology, and urinalysis variables, and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. These analyses revealed no clinically important changes in laboratory test parameters associated with Lexapro treatment. **ECG Changes** Electrocardiograms from Lexapro (N=625), racemic citalopram (N=351), and placebo (N=527) groups were compared with respect to (1) mean change from baseline in various ECG parameters and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. These analyses revealed (1) a decrease in heart rate of 2.2 bpm for Lexapro and 2.7 bpm for racemic citalopram, compared to an increase of 0.3 bpm for placebo and (2) an increase in QTc interval of 3.9 msec for Lexapro and 3.7 msec for racemic citalopram, compared to 0.5 msec for placebo. Neither Lexapro nor racemic citalopram were associated with the development of clinically significant ECG abnormalities. **Other Events Observed During the Premarketing Evaluation of Lexapro** Following is a list of WHO terms that reflect treatment-emergent adverse events, as defined in the introduction to the ADVERSE REACTIONS section, reported by the 1,420 patients treated with Lexapro for periods of up to one year in double-blind or open-label clinical trials during its premarketing evaluation. All reported events are included except those already listed in Tables 2 & 3, those occurring in only one patient, event terms that are so general as to be uninformative, and those that are unlikely to be drug related. It is important to emphasize that, although the events reported occurred during treatment with Lexapro, they were not necessarily caused by it. Events are further categorized by body system and listed in order of decreasing frequency according to the following definitions: frequent adverse events are those occurring on one or more occasions in at least 1/100 patients; infrequent adverse events are those occurring in less than 1/100 patients but at least 1/1,000 patients. Cardiovascular - Frequent: palpitation, hypertension. Infrequent: bradycardia, tachycardia, ECG abnormal, flushing, varicose vein. Central and Peripheral Nervous System Disorders - Frequent: light-headed feeling, migraine. Infrequent: tremor, vertigo, restless legs, shaking, twitching, dysequilibrium, tics, carpal tunnel syndrome, muscle contractions involuntary, sluggishness, coordination abnormal, faintness, hyperreflexia, muscular tone increased. Gastrointestinal Disorders - Frequent: heartburn, abdominal cramp, gastroenteritis. Infrequent: gastroesophageal reflux, bloating, abdominal discomfort, dyspepsia, increased stool frequency, belching, gastritis, hemorrhoids, gagging, polyposis gastric, swallowing difficult. General - Frequent: allergy, pain in limb, fever, hot flashes, chest pain. Infrequent: edema of extremities, chills, lightness of chest, leg pain, asthenia, syncope, malaise, anaphylaxis, fall. Hematologic and Lymphatic Disorders - Infrequent: bruise, anemia, nosebleed, hematoma, lymphadenopathy cervical. Metabolic and Nutritional Disorders - Frequent: increased weight. Infrequent: increased weight, hyperglycemia, thirst, bilirubin increased, hepatic enzymes increased, gout, hypercholesterolemia. Musculoskeletal System Disorders - Frequent: arthralgia, myalgia. Infrequent: jaw stiffness, muscle cramp, muscle stiffness, arthritis, muscle weakness, back discomfort, arthropathy, jaw pain, joint stiffness. Psychiatric Disorders - Frequent: appetite increased, lethargy, irritability, concentration impaired. Infrequent: jitteriness, panic reaction, agitation, apathy, forgetfulness, depression aggravated, nervousness, restlessness aggravated, suicide attempt, amnesia, anxiety attack, bruising, carbohydrate craving, confusion, depersonalization, disorientation, emotional lability, feeling unreal, tremulousness nervous, crying abnormal, depression, excitability, auditory hallucination, suicidal tendency. Reproductive Disorders/Female - Frequent: menstrual cramps, menstrual disorder. Infrequent: menorrhagia, breast neoplasm, pelvic inflammation, premenstrual syndrome, spotting between menses. *% based on female subjects only. †N= 905 Respiratory System Disorders - Frequent: bronchitis, sinus congestion, coughing, nasal congestion, sinus headache. Infrequent: asthma, breath shortness, laryngitis, pneumonia, tracheitis. Skin and Appendages Disorders - Frequent: rash. Infrequent: pruritus, acne, alopecia, eczema, dermatitis, dry skin, folliculitis, ligoma, furunculosis, dry lips, skin nodule. Special Senses - Frequent: vision blurred, tinnitus. Infrequent: taste alteration, earache, conjunctivitis, vision abnormal, dry eyes, eye irritation, visual disturbance, eye infection, pupils dilated, metallic taste. Urinary System Disorders - Frequent: urinary frequency, urinary tract infection. Infrequent: urinary urgency, kidney stone, dysuria, blood in urine. **Events Reported Subsequent to the Marketing of Escitalopram** - Although no causal relationship to escitalopram treatment has been found, the following adverse events have been reported to have occurred in patients and to be temporally associated with escitalopram treatment during post marketing experience and were not observed during the premarketing evaluation of escitalopram: abnormal gait, acute renal failure, aggression, akathisia, allergic reaction, anger, angioedema, atrial fibrillation, chorea, choreoathetosis, delirium, delusion, diplopia, dysarthria, dyskinesia, dystonia, ecchymosis, erythema multiforme, extrapyramidal disorders, fulminant hepatitis, hepatic failure, hypoaesthesia, hypoglycemia, hypokalemia, INR increased, gastrointestinal hemorrhage, glaucoma, grand mal seizures (or convulsions), hemolytic anemia, hepatic necrosis, hepatitis, hypotension, leucopenia, myocardial infarction, myoclonus, neuroleptic malignant syndrome, nightmare, nystagmus, orthostatic hypotension, pancreatitis, paranoia, photosensitivity reaction, priapism, prolactinemia, prothrombin decreased, pulmonary embolism, QT prolongation, rhabdomyolysis, seizures, serotonin syndrome, SIADH, spontaneous abortion, Stevens Johnson Syndrome, tardive dyskinesia, thrombocytopenia, thrombosis, torsade de pointes, toxic epidermal necrolysis, ventricular arrhythmia, ventricular tachycardia and visual hallucinations.

Learned from H. Lundbeck A/S

Rev. 07/07

© 2007 Forest Laboratories, Inc.

Inspector General Faults Specialty Hospital EDs

BY ALICIA AULT
Associate Editor, Practice Trends

Physician-owned specialty hospitals are largely unprepared to handle emergencies and should be more closely tracked by the government to ensure that they comply with Medicare rules, according to a report from the Inspector General of the Department of Health and Human Services.

The IG’s office reviewed written policies for managing medical emergencies, staffing schedules, and staffing policies for 8 days at 109 physician-owned facilities that were identified from a list provided by the Centers for Medicare and Medicaid Services. There are an unknown number of physician-owned specialty hospitals, according to the IG, which is urging the CMS to begin compiling a list.

Of the 109 hospitals surveyed, 66 were surgical, 23 were orthopedic, and 20 were cardiac hospitals. Eighteen of the cardiac hospitals had an emergency department; only 11 of the 23 orthopedic hospitals and 31 of the surgical hospitals had an ED. Thirty-three of the 109 hospitals were in Texas, 15 were in Louisiana, 9 in Oklahoma, 9 in Kansas, and 8 in South Dakota. The rest were spread across other states.

While half of the physician-owned hospitals surveyed had an emergency department, more than half of those EDs only had a single bed. Only 45% of the EDs had a physician on site at all times.

Ninety-three percent of the hospitals met Medicare staffing requirements: having a registered nurse on duty at all times, and a physician on call at all times. But seven hospitals did not have an RN on

duty, and one hospital did not have a physician on call or on duty on at least 1 of the 8 days reviewed.

Two-thirds of the hospitals told staff to call 911 in case of emergency.

While transferring a patient with an emergent problem to another hospital’s ED is acceptable, it might be a violation of Medicare conditions of participation if a hospital uses 911 to obtain medical assistance to stabilize a patient, according to the IG. Thirty-seven of the 109 hospitals (34%) engaged in that practice, the IG reported.

A hospital also is not in compliance if it uses 911 as a substitute for providing services required by the conditions of Medicare participation, noted the IG.

Almost 25% of the hospitals did not address in written policies the “appraisal of emergencies, initial treatment of emergencies, or referral and transfer of patients,” according to the report.

The IG urged the CMS to enforce Medicare staffing requirements. Hospitals should also have information in their written policies on how to manage a medical emergency, such as how to use emergency response equipment or how to follow life-saving protocols, said the IG.

The CMS issued a written response to the IG that was included in the report. The agency said it agreed with the IG’s recommendations and that it would examine current compliance through its routine hospital surveys. As many as 42% of the 109 hospitals would not be subject to CMS oversight, however, according to the IG. Those facilities were instead accredited by the Joint Commission or the American Osteopathic Association.

Finally, the CMS said it would use its ext-

isting authority to require hospitals to have written policies and procedures on managing emergencies, but that it would also consider whether regulatory changes are needed to establish specific requirements for equipment and staff qualifications.

The report was requested by the Senate Finance Committee, whose leaders—Sen. Chuck Grassley (R-Iowa) and Sen. Max Baucus (D-Mont.)—have a history of seeking restrictions on physician-owned specialty hospitals, and have successfully implemented moratoriums on new facilities.

These senators will likely introduce a new proposal to rein in specialty hospitals this spring, Molly Sandvig, executive director of Physician Hospitals of America, said in an interview.

Ms. Sandvig said that her organization—which represents 108 physician-owned facilities—believed that all hospitals should meet Medicare conditions of participation. However, not every hospital should have an emergency department, she said.

While transfers may be acceptable, “No hospital should use 911 as a substitute for providing proper care to patients,” said Ms. Sandvig. That practice is very limited, she said, alleging that the IG had misrepresented facilities’ policies and practices.

Both the American Hospital Association and the Federation of American Hospitals pounced on the report, saying that it shows that physician-owned facilities are a threat to patient safety. “The report illustrates yet another reason why Congress needs to take action in the best interests of patients and ban physician self-referral to new limited-service hospitals they own and operate,” AHA Executive Vice President Rick Pollack said in a statement. ■