

Palliative Care Gets ABMS Nod as Subspecialty

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New York Bureau

The field of palliative care took a major step forward in September when members of the American Board of Medical Specialties voted to approve hospice and palliative medicine as a recognized subspecialty.

The application to recognize the subspecialty had broad support and was cosponsored by 10 medical specialty boards.

As a result, physicians in a number of specialties—including internal medicine, family medicine, pediatrics, psychiatry, neurology, surgery, emergency medicine, and obstetrics and gynecology—will be able to seek the certification.

The first certification examination is expected to be administered in 2008, according to Dr. F. Daniel Duffy, senior adviser to the president of the American Board of Internal Medicine. “It’s going to be a real boost to patient care,” Dr. Duffy said.

The milestone is just the latest in a series of developments in the size and status of the field of palliative care.

Between 2000 and 2004, the number of hospital-owned palliative care programs in the United States increased by nearly 75%, jumping from 632 in 2000 to 1,102 in 2004.

As of 2004, 63% of large hospitals—those with at least 200 general adult beds—reported that they had some type of palliative care program in operation, according to the Center to Advance Palliative Care.

This summer, palliative medicine received a nod from the Accreditation Council for Graduate Medical Education (ACGME) when the organization voted to approve an accreditation process for hospice and palliative medicine fellowship training programs.

ACGME is expected to begin accepting applications in summer 2007.

“We’re well beyond the tipping point,” said Dr. Diane Meier, director of the Center to Advance Palliative Care and director of the Hertzberg Palliative Care Institute at Mount Sinai School of Medicine in New York.

At her institution, palliative care has become so well accepted that asking for a palliative care consult is as routine as calling for an infectious disease consult.

Physicians no longer see it as a personal failure in their treatment of the patient to get assistance from palliative care, she said.

Now the focus has shifted from selling the concept of palliative medicine to ensuring that programs around the country have consistently high standards, Dr. Meier said.

Work is already underway in this area. The National Consensus Project for Quality Palliative Care, which is sponsored by three national palliative medicine organizations, has released quality guidelines.

These guidelines include having interdisciplinary teams, making grief and bereavement services available to patients and families, and providing evidence-based pain and symptom relief, among others.

The standards are a guidepost but will be challenging for smaller programs, Dr. Meier said, and should be filtered by the size of the facility, the staff available, and the needs of the institution.

The National Quality Forum approved its own framework for palliative and hospice care earlier this year.

“That’s real legitimacy,” Dr. Meier commented.

In an effort to ensure that new programs have high-quality processes in place, the Center to Advance Palliative Care launched the Palliative Care Leadership Centers—six centers of excellence in palliative care around the country that train teams of health care providers.

The program includes intensive, 2-day training sessions in which teams are sent to one of the six centers and leaders at the centers act as mentors for a year after training.

The cost of the program is about \$1,750 for a four-person team.

When the site visits started in 2004, Dr. Meier and others at the Center to Advance Palliative Care estimated that about 30% of the teams trained would successfully establish a program, she said, but it’s been closer to 70% to date.

However, the process isn’t fast, and it sometimes takes more than a year for teams to get their programs up and running, she said.

The Mount Carmel Health System in Columbus, Ohio, is one of the six leadership centers. The program was launched in 1997 in an effort to treat patients with serious, advanced diseases who were not candidates for hospice care, Mary Ann Gill, executive director of palliative care services at Mount Carmel, said.

The Mount Carmel program, which includes a palliative care consult team as well as three dedicated palliative care units across three hospitals, is popular with teams working to start programs in community hospitals.

During the training, the members of a palliative care team are encouraged to get to know each other better and begin drafting a work plan to take back to their institution.

The training focuses on the clinical aspects of the program, as well as on financial management and how to sustain the program, Ms. Gill said.

While much of the interest in palliative medicine has been from physicians at mid-career, there is increasing interest among young physicians and residents, said Dr. Philip H. Santa-Emma, medical director for the palliative care service at Mount Carmel. “I’ve seen a huge increase in the number of residents coming through,” he said.

But the training of new physicians in palliative care also represents one of the next big challenges in the field, Dr. Meier said.

Currently there is a cap on the number of residency positions funded by Medicare, making it hard for a new subspecialty to gain a foothold, she said. Palliative care fellowships are currently funded by philanthropy.

As the field continues to move forward, there also needs to be continual education of the health care team about when to get palliative care involved, Dr. Santa-Emma said.

This is a message that has to get out to all members of the health care team, not just physicians, he said.

And members of the palliative care team need to figure out better ways to integrate their care into the intensive care unit and the emergency department, he said. ■

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Vigamox®

(moxifloxacin hydrochloride ophthalmic solution) 0.5% as base

DESCRIPTION: VIGAMOX® (moxifloxacin HCl ophthalmic solution) 0.5% is a sterile ophthalmic solution. It is an 8-methoxy fluoroquinolone anti-infective for topical ophthalmic use.

Clinical Studies: In two randomized, double-masked, multicenter, controlled clinical trials in which patients were dosed 3 times a day for 4 days, VIGAMOX® solution produced clinical cures on day 5-6 in 66% to 69% of patients treated for bacterial conjunctivitis. Microbiological success rates for the eradication of the baseline pathogens ranged from 84% to 94%. Please note that microbiologic eradication does not always correlate with clinical outcome in anti-infective trials.

INDICATIONS AND USAGE: VIGAMOX® solution is indicated for the treatment of bacterial conjunctivitis caused by susceptible strains of the following organisms:

Aerobic Gram-positive microorganisms:

*Corynebacterium species**, *Micrococcus luteus**, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Staphylococcus haemolyticus*, *Staphylococcus hominis*, *Staphylococcus warneri**, *Streptococcus pneumoniae*, *Streptococcus viridans* group

Aerobic Gram-negative microorganisms:

*Acinetobacter lwoffii**, *Haemophilus influenzae*, *Haemophilus parainfluenzae**

Other microorganisms:

Chlamydia trachomatis

*Efficacy for this organism was studied in fewer than 10 infections.

CONTRAINDICATIONS: VIGAMOX® (moxifloxacin HCl ophthalmic solution) is contraindicated in patients with a history of hypersensitivity to moxifloxacin, to other quinolones, or to any of the components in this medication.

WARNINGS: NOT FOR INJECTION.

VIGAMOX® solution should not be injected subconjunctivally, nor should it be introduced directly into the anterior chamber of the eye.

In patients receiving systemically administered quinolones, including moxifloxacin, serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported, some following the first dose. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, angioedema (including laryngeal, pharyngeal or facial edema), airway obstruction, dyspnea, urticaria, and itching. If an allergic reaction to moxifloxacin occurs, discontinue use of the drug. Serious acute hypersensitivity reactions may require immediate emergency treatment. Oxygen and airway management should be administered as clinically indicated.

PRECAUTIONS: General: As with other anti-infectives, prolonged use may result in overgrowth of non-susceptible organisms, including fungi. If superinfection occurs, discontinue use and institute alternative therapy. Whenever clinical judgment dictates, the patient should be examined with the aid of magnification, such as slit-lamp biomicroscopy, and, where appropriate, fluorescein staining. Patients should be advised not to wear contact lenses if they have signs and symptoms of bacterial conjunctivitis.

Information for Patients: Avoid contaminating the applicator tip with material from the eye, fingers or other source.

Systemically administered quinolones including moxifloxacin have been associated with hypersensitivity reactions, even following a single dose. Discontinue use immediately and contact your physician at the first sign of a rash or allergic reaction.

Drug Interactions: Drug-drug interaction studies have not been conducted with VIGAMOX® solution. *In vitro* studies indicate that moxifloxacin does not inhibit CYP3A4, CYP2D6, CYP2C9, CYP2C19, or CYP1A2 indicating that moxifloxacin is unlikely to alter the pharmacokinetics of drugs metabolized by these cytochrome P450 isozymes.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term studies in animals to determine the carcinogenic potential of moxifloxacin have not been performed. However, in an accelerated study with initiators and promoters, moxifloxacin was not carcinogenic in rats following up to 38 weeks of oral dosing at 500 mg/kg/day (approximately 21,700 times the highest recommended total daily human ophthalmic dose for a 50 kg person, on a mg/kg basis). Moxifloxacin was not mutagenic in four bacterial strains used in the Ames *Salmonella* reversion assay. As with other quinolones, the positive response observed with moxifloxacin in strain TA 102 using the same assay may be due to the inhibition of DNA gyrase. Moxifloxacin was not mutagenic in the CHO/HGPRT mammalian cell gene mutation assay. An equivocal result was obtained in the same assay when v79 cells were used. Moxifloxacin was clastogenic in the v79 chromosome aberration assay, but it did not induce unscheduled DNA synthesis in cultured rat hepatocytes. There was no evidence of genotoxicity *in vivo* in a micronucleus test or a dominant lethal test in mice.

Moxifloxacin had no effect on fertility in male and female rats at oral doses as high as 500 mg/kg/day, approximately 21,700 times the highest recommended total daily human ophthalmic dose. At 500 mg/kg orally, there were slight effects on sperm morphology (head-tail separation) in male rats and on the estrous cycle in female rats.

Pregnancy:

Teratogenic Effects. Pregnancy Category C: Moxifloxacin was not teratogenic when administered to pregnant rats during organogenesis at oral doses as high as 500 mg/kg/day (approximately 21,700 times the highest recommended total daily human ophthalmic dose); however, decreased fetal body weights and slightly delayed fetal skeletal development were observed. There was no evidence of teratogenicity when pregnant Cynomolgus monkeys were given oral doses as high as 100 mg/kg/day (approximately 4,300 times the highest recommended total daily human ophthalmic dose). An increased incidence of smaller fetuses was observed at 100 mg/kg/day.

Since there are no adequate and well-controlled studies in pregnant women, VIGAMOX® solution should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: Moxifloxacin has not been measured in human milk, although it can be presumed to be excreted in human milk. Caution should be exercised when VIGAMOX® solution is administered to a nursing mother.

Pediatric Use: The safety and effectiveness of VIGAMOX® solution in infants below 1 year of age have not been established.

There is no evidence that the ophthalmic administration of VIGAMOX® has any effect on weight bearing joints, even though oral administration of some quinolones has been shown to cause arthropathy in immature animals.

Geriatric Use: No overall differences in safety and effectiveness have been observed between elderly and younger patients.

ADVERSE REACTIONS: The most frequently reported ocular adverse events were conjunctivitis, decreased visual acuity, dry eye, keratitis, ocular discomfort, ocular hyperemia, ocular pain, ocular pruritus, subconjunctival hemorrhage, and tearing. These events occurred in approximately 1-6% of patients. Nonocular adverse events reported at a rate of 1-4% were fever, increased cough, infection, otitis media, pharyngitis, rash, and rhinitis.

Reference:

1. Data on file. Alcon Laboratories, Inc. 2005.

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