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handicapped access for children with special needs? Is there well-supervised recreation for the children after school and on weekends? Does the local Little League allow softer baseballs for young T-ball players who can all smack a ball off a tee, but who don't always have reflexes to protect their faces when a rocket is launched from the tee in their direction? And remember that when you delve into these arenas, the state AAP chapter and the national offices likely will have resources available to give you verbal ammunition and research statistics for confronting intransigent "status quo" advocates.

For many of you, office and local involvement will be the limit of your advocacy activities—and that's fine. You are working on behalf of patients, and it is a good feeling to have accomplished something positive for the children. But some may want to pursue advocacy further into state and/or national issues affecting children.

For those of you with the passion for single or multiple issues on those fronts, I would recommend involvement with your state AAP chapter as well as the national organization. AAP chapters in particular are always looking for passionate pediatricians (we are all *compassionate* but not all have extra passion for advocacy) to spearhead a project or idea.

Most chapters interact regularly with governmental leaders because there are many legislative items that affect our professional lives as well as those of our pa-

tients. Chapter involvement is of critical importance to ensuring that well-meaning legislators, who may be led astray by persuasive and detrimental special interests, are educated about legitimate science and proper quality of care; that often requires the advocacy of an informed pediatrician.

If you have an interest in a particular issue and can find the time, then by all means get involved with your chapter. Who knows? You may even like it to the point where you continue to work through your state AAP chapter or the national organization—it is professionally and personally satisfying.

For those of you who are winding down in your office professional lives, consider working for your state chapter. For those of you unfamiliar with government workings, be aware that there is often a request for testimony about a pediatric-related issue with only a few days' notice. (I have always wondered as to why the short notice—legislators know weeks in advance about certain agenda items that are up for discussion, yet they only tell professional organizations a few days in advance. It makes no sense to me!) It is difficult for full-time practitioners to cancel patients on short notice and run to the capital to advocate on an important issue. However, for those of you seasoned veterans who are cutting back and only working a few days a week, you may have time to testify on short notice.

Don't worry that you may not have the facts at your fingertips for the issue at hand; National AAP can be very helpful in pro-

viding you with talking points and facts and almost completely written testimony on a moment's notice. Your AAP chapter is also good at using the national organization's resources and its local expertise to synthesize testimony and speaking points. All you would need is the time to appear. Each state chapter needs a cadre of veteran pediatricians upon whom it can rely to promote child (and sometimes pediatrician) issues and/or legislation on short notice. If you have the time, they have the need.

Advocacy is an important part of every pediatrician's professional life. It may involve working for the welfare of your patients by helping them navigate the insur-

ance morass; it may be participation in a Child Study Team on behalf of a patient with a school problem. It may involve community, state, or national organizations and issues. Whatever the issue and whatever the venue, I urge all of you to get involved and help. Your time and your expertise absolutely can make a difference. You will feel great satisfaction—and that's priceless!

DR. SCOTT is in private practice in Medford, N.J., and is a member of the Pediatric News Editorial Advisory Board. Send your comments or questions to Dr. Scott at our editorial offices (pdnews@elsevier.com).

AAP chapters are always looking for passionate pediatricians (we are all compassionate but not all have passion for advocacy) to spearhead a project.

Bronchopulmonary Dysplasia Clinic Reduces Readmissions, Saves Money

TORONTO — The establishment of an interdisciplinary outpatient clinic for patients with bronchopulmonary dysplasia can significantly improve care and decrease hospital readmissions, reported Dr. Stephen Welty of Columbus Children's Hospital.

Before the establishment of his hospital's outpatient clinic, an analysis of 269 children with bronchopulmonary dysplasia (BPD) discharged to their general follow-up clinic in 2003 revealed that 29% were readmitted within 1 month of discharge, Dr. Welty said at the annual meeting of the Pediatric Academic Societies.

"When we first saw that number we were horrified," he said. "And for two of those patients their stay [after readmission] was about 6 months, which was quite alarming."

Staff felt that factors contributing to the high readmission rate included family anxiety and lack of education about caring for their child at home, medical conditions such as reactive airway disease, and resource issues such as living remotely. In addition, BPD patients have complex, multidisciplinary needs that require social, nutritional, and developmental specialists, said Dr. Welty.

"Our hypothesis was that by seeing children at regular scheduled intervals in an interdisciplinary BPD clinic, we would reduce readmission rates," he said.

The BPD clinic staff saw all patients before discharge to assess the adequacy of oxygenation and whether discharge was realistic, and then saw them again 2 weeks after discharge to reevaluate. A study comparing outcomes within 30 days of discharge found that readmissions went from 29% before the establishment of the BPD clinic, to 3% the first year after its establishment, 6% the second year, and 5% the third year. Dr. Welty suggested this reduction in readmissions was mostly due to the prevention of pulmonary exacerbations.

The study estimated that the BPD clinic resulted in a cost saving of \$2.5 million to \$3 million per year based on the fact that the average length of stay on readmission was 19 days, with an average cost of \$53,600 per patient. The average cost of a BPD clinic visit is \$533.

"We believe other potential benefits of the clinic are improved family satisfaction, improved feeding, nutrition and growth, and improved developmental outcomes," he added.

—Kate Johnson

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 PHARMACOLOGY:

Microbiology:

The following *in vitro* data are also available, but their clinical significance in ophthalmic infections is unknown. The safety and effectiveness of VIGAMOX® solution in treating ophthalmological infections due to these microorganisms have not been established in adequate and well-controlled trials.

The following organisms are considered susceptible when evaluated using systemic breakpoints. However, a correlation between the *in vitro* systemic breakpoint and ophthalmological efficacy has not been established. The list of organisms is provided as guidance only in assessing the potential treatment of conjunctival infections. Moxifloxacin exhibits *in vitro* minimal inhibitory concentrations (MICs) of 2 µg/ml or less (systemic susceptible breakpoint) against most (≥ 90%) of strains of the following ocular pathogens.

Aerobic Gram-positive microorganisms:

Listeria monocytogenes
Staphylococcus saprophyticus
Streptococcus agalactiae
Streptococcus mitis
Streptococcus pyogenes
Streptococcus Group C, G and F

Anaerobic microorganisms:

Clostridium perfringens
Fusobacterium species
Prevotella species
Propionibacterium acnes
Other microorganisms:
Chlamydia pneumoniae
Legionella pneumophila
Mycobacterium avium
Mycobacterium marinum
Mycoplasma pneumoniae

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

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

CONTRAINDICATIONS: VIGAMOX® 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® solution 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.

References:

1. Data on file. Alcon Laboratories, Inc. 2005.
2. VIGAMOX® solution prescribing information.

Rx Only

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