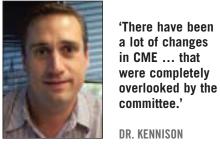
IOM Calls for Continuing Education Institute

BY JOYCE FRIEDEN

public-private institution launched by the Department of Health and Human Services would be the best way to raise standards and quality for continuing health education, according to a report issued by the Institute of Medicine.

There are serious flaws in the way that continuing education for physicians and other health professionals is "conducted, financed, regulated. and evaluated." concluded the authors of the 200-

44



page report "Redesigning Continuing Education in the Health Professions." They added, "The science underpinning continuing education for health professionals is fragmented and underdeveloped."

Because of that, "establishing a national interprofessional continuing education institute is a promising way to foster improvements in how health professionals carry out their responsibilities," the authors said.

The 14-member Institute of Medicine

<u>Pataday</u>

(olopatadine hydrochloride ophthalmic solution) 0.2%

INDICATIONS AND USAGE PATADAYTM solution is indicated for the treatment of ocular itching associated with allergic conjunctivitis.

CONTRAINDICATIONS

Hypersensitivity to any components of this product WARNINGS

For topical ocular use only. Not for injection or oral use

PRECAUTIONS Information for Patients As with any eye drop, to prevent contaminating the dropper tip and solution, care should be taken not to touch the eyelids or surrounding areas with the dropper tip of the bottle. Keep bottle tightly closed when not in use. Patients should be advised not to wear a contact lens if their eye is ref.

eye is red. PATADAYTM (olopatadine hydrochloride ophthalmic solution) 0.2% should not be used to treat contact lens related irritation. The preservative in PATADAYTM solution, benzalkonium chloride, may be absorbed by soft contact lenses. Patients who wear soft contact lenses and **whose eyes are not red**, should be instructed to wait at least the minute of the instilled interaction by the patients who where hold in the soft of the instructed to wait at least the minute of the instilled by the patient of the instructed to wait at least eye is red. PATADAY™ (olopata ten minutes after instilling PATADAYTM (olopatadine hydrochloride ophthalmic solution) 0.2% before they insert their contact lenses.

ophthalmic solution) 0.2% before they insert their contact lenses. **Carcinogenesis, Mutagenesis, Impairment of Fertility** Olopatadine administered orally was not carcinogenic in mice and rats in doses up to 500 mg/kg/day and 200 mg/kg/day, respectively. Based on a 40 µL drop size and a 50 kg person, these doses were approximately 150,000 and 50,000 times higher than the maximum recommended ocular human dose (MROHD). No mutagenic potential was observed when olopatadine was tested in an *in vitro* bacterial reverse mutation (Ames) test, an *in vitro* mammalian chromosome aberration assay or an in vivo mouse micronucleus test. Olopatadine administered to male and female rats at oral doses of approximately 100,000 times MROHD level resulted in a slight decrease in the fertility index and reduced implantation rate; no effects on reproductive function were observed at doses of approximately 15,000 times the MROHD level.

Pregnancy:

Pregnancy: Teratogenic effects: Pregnancy Category C Olopatadine was found not to be teratogenic in rats and rabbits. However, rats treated at 600 mg/kg/day, or 150,000 times the MROHD and rabbits treated at 400 mg/kg/day, or approximately 100,000 times the MROHD, during organogenesis showed a decrease in live fetuses. In addition, rats treated with 600 mg/kg/day of olopatadine during organogenesis showed a decrease in fetal weight. Further, rats treated with 600 mg/kg/day of olopatadine during late gestation through the lactation period showed a decrease in neonatal survival and body weight

weight. There are, however, no adequate and well-controlled studies in pregnant women. Because animal studies are not always predictive of human responses, this drug should be used in pregnant women only if the potential benefit to the mother justifies the potential risk to the embryo or fetus.

Nursing Mothers: Olopatadine has been identified in the milk of nursing rats following oral administration. It is not known whether topical ocular administration could result in sufficient systemic absorption to produce detectable quantities in the human breast milk. Nevertheless, caution should be exercised when PATADAY™ (olopatadine hydrochloride ophthalmic solution) 0.2% is administered to a nursing mother.

committee that produced the report proposed the creation of a public-private entity that would involve the full spectrum of stakeholders in health care delivery and continuing education.

That new entity, which would be called the Continuing Professional Development Institute (CPDI), would look at new financing mechanisms to help avoid po-

tential conflicts of interest. The institute also would develop priorities for research in continuing health education and recognize effective education models The medical

community must move from a culture of continuing education to one of "continuing professional development ... stretching from the classroom to the point of care, shifting control of learning to individual practitioners, and [adapting] to the individual's learning needs," said committee chair Dr. Gail Warden.

We believe that academic institutions need to be much more engaged than they have been in continuing education," Dr. Warden, president emeritus of the

Pediatric Use Safety and effectiveness in pediatric patients below the age of 3 years have not been established.

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

ADVERSE REACTIONS

similar to cold syndrome and pharyngitis were reported at an Synthetic and phase of the phas

The following auverse expensions: and patients: *Ocular*: blurred vision, burning or stinging, conjunctivitis, dry eye, foreign body sensation, hyperemia, hypersensitivity, keratitis, lid edema, pain and ocular pruritus. *Non-ocular*: asthenia, back pain, flu syndrome, headache, increased cough, infection, nausea, rhinitis, sinusitis and taste perversion. Some of these events were similar to the underlying disease being sturied

DOSAGE AND ADMINISTRATION The recommended dose is one drop in each affected eye once a day.

HOW SUPPLIED

HOW SUPPLIED PATADAYTM (olopatadine hydrochloride ophthalmic solution) 0.2% is supplied in a white, oval, low density polyethylene DROP-TAINER® dispenser with a natural low density polyethylene dispensing plug and a white polyporpylene cap. Tamper evidence is provided with a shrink band around the closure and neck area of the package. NDC 0065-0272-25

2.5 mL fill in 4 mL oval bottle

Storage: Store at 2°C to 25°C (36°F to 77°F) U.S. Patents Nos. 4,871,865; 4,923,892; 5,116,863; 5,641,805; 6,995,186

Rx Only

1. Abelson MB, Gomes PJ, Pasquine T, et al. Efficacy of olopatadine Aueson way, Gonies PJ, Pasquine T, et al. Princady of outpatialine ophthalmic solution 0.2% in reducing signs and symptoms of allergic conjunctivitis. *Allergy Asthma Proc.* 2007;28:427-433.
PATADAY" Solution Package Insert.
Vogelson CT, Abelson MB, Pasquine T, et al. Preclinical and clinical antiallergic effect of olopatadine 0.2% solution 24 hours after topical

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- Wolters Kluwer Health, Source® Pharmaceutical Audit Suite. September 2008-August 2009.



TAKE

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Henry Ford Health System, Detroit, said during a teleconference. "The system should engender coordination and collaboration among professions that should provide higher quality for a given amount of resources and lead to improvements in patient health and safety."

New Report for Old CME Model?

Continuing medical education (CME) vendors had mixed reactions to the committee's report.

Rick Kennison, D.P.M., president and general manager of PeerPoint Medical Education Institute, said that he agreed with the committee's recommendations in the area of traditional CME. Those types of programs, such as live meetings and society annual meetings, "are didactic in nature [and] don't meet the needs of participants as learners, and there is conflict and bias associated with them."

But a large problem with the report is that the committee reviewed continuing medical education as it used to be, Dr. Kennison said. "They wanted to evaluate a model of a car, but instead of using a 2010 model, they used a 2006 model," he said. "There have been a lot of changes in CME in the course of the last few years that were completely overlooked by the committee."

For example, Dr. Kennison said that his organization has already moved to performance-improvement CME, which is a goal outlined in the report. Performance-improvement CME, he explained, involves "direct learning by the participant-self-directed learning-in which the participant uses metrics and supplies data to help determine change and improvement in patient care.

'We've been doing this for more than 2 years now," he noted. "Because the group didn't evaluate performance-improvement CME, I think they missed a

major stepping-stone associated with the current status of CME."

Dr. Kennison said his company's CME programs are sponsored by the pharmaceutical industry. But the funding is in the form of general grants related to diseases and conditions, he noted, and does not involve sponsoring education initiatives that highlight specific drugs or classes of drugs.

Dr. Edmond Cleeman, a New York orthopedic surgeon and founder of TRI-ARQ, a medical education organization for orthopedists, physical therapists, and other orthopedic health professionals, agreed with the committee's recommendation that continuing health education needs to be team based and multidisciplinary. In the TRIARQ program, which is still being developed, students will pay for courses themselves.

"We felt strongly about developing a community that is really across disciplines. Doctors have things that we can learn from physical therapists too," he said. For example, physicians and physical therapists can work together to develop the best exercises for patients in pain.

Leery of a Government Committee

On the other hand, some of the recommendations gave Dr. Cleeman pause.

To form another government committee and force a single type of a mold, and add additional regulations on all medical subspecialties and on CMEthat's not the right approach," he said.

Instead, "I think it's a good idea to have a private organization, maybe like the American Medical Association," Dr. Cleeman said. "Their goal would be to assist in developing goals for continuing education."

The report, which was sponsored by the Josiah Macy, Jr. Foundation, is available at www.iom.edu/continuinged.

Examine Effectiveness, Cost of CME

The proposed institute could L have a dramatic effect on con-

tinuing "education" requirements for internists and other health care professionals. Through the establishment of a professionally inclusive publicprivate institute, research on the effectiveness of continuing education models could inform the health professional com-

munity about how best to develop educational programs and continuing professional competencies.

Although interdisciplinary health team education might improve health outcomes for patients, it's difficult to assess the value of single interventions on patient outcomes. Also, each profession, such as medicine, nursing, and pharmacy, will continue to have specific needs for professional education.



uing Medical Education. Their modified programs involve active learning and outcomes evaluation, and avoid potential conflicts of interest associated with financial support by the pharmaceutical and med-

ical device industries.

However, in an era of economic constraints, particularly for primary care providers, new standards developed by any organization must consider not only educational efficacy but also efficiency and cost.

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Several institutions have embraced the newest standards of the Accreditation Council for Contin-

