

# Mandating Flu Shots Gets the Job Done

BY MIRIAM E. TUCKER

Strategies that compel health care personnel to receive an influenza immunization were shown to successfully increase vaccination rates to nearly 100% in two U.S. studies.

Results from these studies—one involving a large health care system, the other a single hospital—were summarized in a telebriefing, a week prior to their full presentations at the 2010 Decennial International Conference on Healthcare-Associated Infections in Atlanta.

Dr. Jonathan Perlin, who is chief medical officer of the Nashville, Tennessee-based Hospital Corporation of America (HCA), presented the results of a “somewhat controversial” mandatory vaccination policy adopted during the 2009-2010 influenza season across the system’s 163 hospitals, 112 outpatient clinics, and 368 medical practices in 20 states.

Two recent lawsuits pertaining to the program were successfully defended, he noted.

The policy required that any employee who would not be vaccinated because of an egg allergy, a history of Guillain-Barré syndrome, or a reli-

## VITALS

**Major Finding:** An influenza immunization mandate increased vaccination rates among hospital employees from a high of 74% to 96% at one institution and from 63% to 91% at another.

**Data Source:** Databases of HCA and Children’s Mercy Hospital and Clinics.

**Disclosures:** Dr. Livingston reported having no conflicts of interest. Dr. Perlin did not disclose whether he had conflicts of interest and could not be reached at press time.

gious/philosophical objection must be either reassigned to nonpatient contact roles or required to wear surgical masks. Webcasts were shown at all facilities explaining the rationale for the program and also introduced nonvaccine strategies such as cough/sneeze etiquette, hand hygiene, proper cleaning techniques, and the importance of staying home when ill (the so-called presenteeism policy).

Prior to the program, seasonal influenza vaccination rates for 2008-2009 influenza season varied across the various HCA facilities from a low of 20% to a high of 74% (mean, 58%).

As of Nov. 1, 2009, 96% of the 140,599 total employees and of the 98,067 clinical employees who were offered the

seasonal influenza vaccine accepted it.

A total of 5,015 employees declined the vaccine, of whom three-fourths gave no reason.

Among those who did give a reason, allergy was the most common (12%).

The vast majority of those who declined wore masks.

“The employee response has been overwhelmingly positive.

... We believe that programs such as ours will become the standard of care,” Dr. Perlin said during the telebriefing.

Similar success was seen at Children’s Mercy Hospital and Clinics, Kansas City, Mo., a freestanding children’s hospital with approximately 5,600 employees. In 2004, the hospital began offering the vaccine free to all employees, along with education about influenza and the importance of vaccination.

Other strategies were introduced subsequently, including mass vaccination days, mobile vaccination carts, flu vaccine “champions” in hospital wards and critical care units, as well as

rewards such as paid days off.

In 2008, the facility introduced a mandatory policy that required employees to either receive the vaccine or formally decline it in writing with an established deadline for compliance, said Dr. Robyn Livingston, director of infection control and prevention at the hospital.

Compared with a vaccination rate of 63% in 2004, introduction of the policy in 2008 resulted in a rate of 85% in the 2008-2009 season, with about 96% overall compliance with the policy.

In the 2009-2010 season, when vaccination with both the seasonal and H1N1 vaccine was started earlier, the vaccination rate increased to 91%, and 99% were compliant with the policy by either receiving the vaccine or formally declining it.

The institution is now considering a fully mandatory influenza vaccination policy—that is, with no allowance for declination—for the next influenza season.

“Though our rates are well above the national average, there is still room for improvement,” Dr. Livingston said. ■

## Flu Shots for School-Age Kids Confers Herd Immunity

BY MARY ANN MOON

Immunizing children aged 3-15 years in isolated rural communities against influenza conferred substantial immunity to unvaccinated members of the communities, according to a report.

“Our findings offer experimental proof to support selective influenza immunization of school-aged children with inactivated influenza vaccine to interrupt influenza transmission. Particularly, if there are constraints in quantity and delivery of vaccine, it may be advantageous to selectively immunize children in order to reduce community transmission of influenza,” said Dr. Mark Loeb of McMaster University, Hamilton, Ont., and his associates.

Observational and computer modeling studies have suggested that such an approach might reduce influenza transmission, but randomized clinical trials to confirm this theory have not been feasible because in most settings, it would be unethical to withhold immunization from children in a control group.

However, rural Hutterite colonies in Western Canada offer a unique setting for such a study. These communities of approximately 60-120 Anabaptist residents are relatively isolated from other populations but show significant influenza activity each winter. The members of 46 Hutterite colonies in Alberta, Saskatchewan, and Manitoba agreed to random assignment to receive either immunization for influenza A and B during the 2008-2009 flu season (22 colonies) or to receive hepatitis

A vaccination as a control (24 colonies).

Only healthy children aged 3-15 years were immunized, because those are the ages at which Hutterite children attend school. Mean vaccine coverage was 83% in this age group. This resulted in 502 children receiving flu vaccine in a population totaling 1,773 and 445 children receiving hepatitis A vaccine in a population totaling 1,500. Other colony members were not immunized, as is customary in Hutterite colonies. This includes community members at high risk of influenza complications such as children aged 23 months and younger, pregnant women, the elderly, and people of all ages with chronic medical conditions.

The primary outcome of this study was the development of laboratory-confirmed influenza A or B in colony members who did not receive flu vaccine. This occurred in 39 members of colonies assigned to influenza immunization (3%), a rate less than half of the 7.6% rate of influenza infection in control colonies.

“The level of indirect vaccine protectiveness was 61%” overall and 49% among high-risk subjects, Dr. Loeb and his colleagues said (JAMA 2010;303:943-50). ■

**Disclosures:** This study was supported by the Canadian Institutes for Health Research and the National Institute for Allergy and Infectious Diseases. Sanofi Pasteur donated vaccines used for the study but provided no funding and had no other role in the study. The authors said they had no conflicts of interest.

## Pataday™ (olopatadine hydrochloride ophthalmic solution) 0.2%

### INDICATIONS AND USAGE

PATADAY™ 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 red.

PATADAY™ (olopatadine hydrochloride ophthalmic solution) 0.2% should not be used to treat contact lens related irritation. The preservative in PATADAY™ 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 ten minutes after instilling PATADAY™ (olopatadine hydrochloride 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 reversion 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:

#### 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.

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.

#### 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

Symptoms similar to cold syndrome and pharyngitis were reported at an incidence of approximately 10%.

The following adverse experiences have been reported in 5% or less of 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 studied.

#### DOSAGE AND ADMINISTRATION

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

#### HOW SUPPLIED

PATADAY™ (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 polypropylene 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

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