Mandatory Flu Shots Urged for Health Workers

BY JANUARY W. PAYNE

All health care workers should be vaccinated annually against influenza, and doing so should be a condition of new or continued employment, according to a position paper from the Society for Healthcare Epidemiology of America.

This is the first time the organization has recommended mandatory vaccination of all health care workers; and its position was also endorsed by the Infectious Diseases Society of America.

"I am very hopeful that this guideline will encourage the adoption of more mandatory policies at all health care institutions," said Dr. Neil Fishman, president of SHEA and director of health care epidemiology and infection control for the University of Pennsylvania Health System, Philadelphia.

A variety of vaccinations already are required at health care facilities, including measles, mumps and rubella, and some facilities also require vaccination against chickenpox, pertussis, and hepatitis B. "So there are precedents for having vaccines as a condition of employment," Dr. Fishman said.

The hope is that SHEA's new recommendation – published Aug. 31 in the journal Infection Control and Healthcare Epidemiology – will improve the current influenza vaccination rates for health care workers, which now hover in the 30%-40% range, Dr. Fishman said. The recommendation applies to all workers, students, and volunteers in all health care facilities, regardless of whether they have direct patient contact.

Under the SHEA position paper, the only exceptions to the mandatory vaccination policy would be for medical reasons, such as a severe allergy to eggs, Dr. Fishman said.

The Centers for Disease Control and Prevention currently recommends that all health care professionals get an annual influenza vaccine and that health care facilities provide the vaccine to its workers with a goal of vaccinating 100% of staff.

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Researchers at the Virginia Mason Medical Center, Seattle – believed to be the first in the country to institute mandatory influenza vaccination for its health care workers in 2005 – recently studied their institution's efforts to improve influenza vaccination rates.

They found that in the first year after the mandatory influenza requirement was put in place, 97.6% of the facility's 4,703 health care workers were vaccinated, followed by adherence rates of more than 98% in the following 4 years. Less than 0.7% of the center's workers were exempted from vaccination for medical or religious reasons, and less than 0.2% refused to be vaccinated or left employment at the center(Infect. Control Hosp. Epidemiol. 2010;31:881-8).

Dr. Fishman reported no conflicts of interest. The authors of SHEA's position paper reported having served as consultants for or having received honoraria from various companies that make vaccines, influenza diagnostics, and pharmaceuticals. ■

Brief Summary of Prescribing Information–See Package Insert for Full Prescribing Information at www.pharmaderm.com

Veregen®
(sinecatechins)
Ointment, 15%
Rx Only

For Topical Dermatologic Use Only

INDICATIONS AND USAGE

Veregen® is indicated for the topical treatment of external genital and perianal warts (*Condylomata acuminata*) in immunocompetent patients 18 years and older.

The safety and effectiveness of Veregen® have not been established for treatment beyond 16-weeks or for multiple treatment courses.

The safety and effectiveness of Veregen® in immunosuppressed patients have not been established.

CONTRAINDICATIONS

None

CLINICAL STUDIES

Two randomized, double-blind, vehicle-controlled studies were performed to investigate the safety and efficacy of Veregen® in the treatment of immunocompetent patients 18 years of age and older with external genital and perianal warts. The subjects applied the ointment 3 times daily for up to 16 weeks or until complete clearance of all warts (baseline and new warts occurring during treatment).

Over both studies the median baseline wart area was 51 mm^2 (range 12 to 585 mm^2), and the median baseline number of warts was 6 (range 2 to 30).

The primary efficacy outcome measure was the response rate defined as the proportion of patients with complete clinical (visual) clearance of all external genital and perianal warts (baseline and new) by week 16, presented in Tables 1 and 2 for all randomized subjects dispensed medication.

Table 1: Efficacy by Region

	Complete Clearance
All Countries (includes the United States)	
Veregen® 15% (*N* = 397)	213 (53.6%)
Vehicle (*N* = 207)	73 (35.3%)
United States	
Veregen® 15% (*N* = 21)	5 (23.8%)
Vehicle (*N* = 9)	0 (0.0%)

Table 2: Efficacy by Gender

	Complete Clearance
Males	
Veregen® 15% (*N* = 205)	97 (47.3%)
Vehicle (*N* = 118)	34 (28.8%)
Females	
Veregen® 15% (*N* = 192)	116 (60.4%)
Vehicle (*N* = 89)	39 (43.8%)

Median time to complete wart clearance was 16 weeks and 10 weeks, respectively, in the two phase 3 clinical trials.

The rate of recurrence of external genital and perianal warts 12 weeks after completion of treatment in subjects with complete clearance is 6.8% (14/206) for those treated with Veregen® and 5.8% (4/69) for those treated with vehicle.

WARNINGS AND PRECAUTIONS

Veregen® has not been evaluated for the treatment of urethral, intra-vaginal, cervical, rectal, or intra-anal human papilloma viral disease and should not be used for the treatment of these conditions.

Use of Veregen® on open wounds should be avoided.

Patients should be advised to avoid exposure of the genital and perianal area to sun/UV-light as Veregen® has not been tested under these circumstances.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category C: There are no adequate and well controlled studies in pregnant women. Veregen® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

It is not known whether topically applied Veregen® is excreted in breast milk.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

Seven patients (1.4%), older than 65 years of age were treated with Veregen® in clinical studies. This, however, is an insufficient number of subjects to determine whether they respond differently from younger subjects.

ADVERSE REACTIONS

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In Phase 3 clinical trials, a total of 397 subjects received Veregen® three times per day topical application for the treatment of external genital and perianal warts for up to 16 weeks.

Serious local adverse events of pain and inflammation were reported in two subjects (0.5%), both women.

In clinical trials, the incidence of patients with local adverse events leading to discontinuation or dose interruption (reduction) was 5% (19/397). These included the following events: application site reactions (local pain, erythema, vesicles, skin erosion/ulceration), phimosis, inguinal lymphadenitis, urethral meatal stenosis, dysuria, genital herpes simplex, vulvitis, hypersensitivity, pruritus, pyodermitis, skin ulcer, erosions in the urethral meatus, and superinfection of warts and ulcers.

Local and regional reactions (including adenopathy) occurring at >1% in the groups treated with Veregen® (*N*=397) or vehicle (*N*=207), respectively, were: erythema (70%, 32%), pruritus (69%, 45%), burning (67%, 31%), pain/discomfort (56%, 14%), erosion/ulceration (49%, 10%), edema (45%, 11%), induration (35%, 11%), rash vesicular (20%, 6%), regional lymphadenitis (3%, 1%), desquamation (5%, <1%), discharge (3%, <1%), bleeding (2%, <1%), reaction (2%, 0%), scar (1%, 0%), irritation (1%, 0%), and rash (1%, 0%).

A total of 266/397 (67%) of subjects in the Veregen® group had either a moderate or a severe reaction that was considered probably related to the drug, of which 120 (30%) subjects had a severe reaction. Severe reactions occurred in 37% (71/192) of women and in 24% (49/205) of men. The percentage of subjects with at least one severe, related adverse event was 26% (86/328) for subjects with genital warts only, 42% (19/45) in subjects with both genital and perianal warts and 48% (11/23) of subjects with perianal warts only.

Phimosis occurred in 3% of uncircumcised male subjects (5/174) treated with Veregen® and in 1% (1/99) in vehicle.

The maximum mean severity of erythema, erosion, edema, and induration was observed by week 2 of treatment.

Less common local adverse events included urethritis, perianal infection, pigmentation changes, dryness, eczema, hyperesthesia, necrosis, papules, and discoloration. Other less common adverse events included cervical dysplasia, pelvic pain, cutaneous facial rash, and staphylococcemia.

In a dermal sensitization study of Veregen® in healthy volunteers, hypersensitivity (type IV) was observed in 5 out of 209 subjects (2.4%) under occlusive conditions.

DOSAGE AND ADMINISTRATION

Veregen® is to be applied three times per day to all external genital and perianal warts. Treatment with Veregen® should be continued until complete clearance of all warts, however no longer than 16 weeks.

HOW SUPPLIED/STORAGE AND HANDLING

Veregen® is a brown ointment and is supplied in an aluminum tube containing 15 grams (NDC # 10337-450-15) of ointment per tube.

Prior to dispensing to the patient, store refrigerated 2°C to 8°C (36°F to 46°F). After dispensing, store refrigerated or up to 25°C (77°F). Do not freeze.

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