Varicella Postexposure Prophylaxis Available

The unlicensed product, VariZIG, should help counteract the dwindling supply of VZIG.

BY KATE JOHNSON
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The dwindling U.S. supply of varicella-zoster immune globulin has been replenished with a new unlicensed product made available under a Food and Drug Administration investigational new drug application, according to the Centers for Disease Control and Prevention.

An expanded access protocol for VariZIG (Cangene Corporation, Winnipeg, Canada) was granted in February as supplies of the only licensed U.S. varicella-zoster immune globulin (VZIG) product began to run out, following its discontinuation last October by the manufacturer, Public Health Biologic Laboratories of Boston.

VariZIG is intended for patients without evidence of immunity who have been exposed to varicella and who are at increased risk for severe disease and complications. The CDC's Advisory Committee on Immunization Practices recommends it for the following groups:

- Immunocompromised patients.
- Neonates whose mothers have signs and symptoms of varicella around the time of delivery (5 days before to 2 days after).
- Premature infants born at or after 28 weeks of gestation who are exposed during the neonatal period and whose mothers do not have evidence of immunity.
- Premature infants born before 28 weeks of gestation or who weigh 1,000 g or more at birth and were exposed during the neonatal period, regardless of maternal history of varicella disease or vaccination.
- Pregnant women.

The product is expected to provide maximum benefit when administered as soon as possible after exposure although it can still be effective if administered up to 96 hours after exposure (MMWR 2006;55[early release]:www.cdc.gov/mmwr).

For other patients not included in the above groups and without evidence of immunity, the varicella vaccine is recommended for prophylaxis within 96 hours and possibly up to 120 hours post exposure, according to the report.

The CDC recommends that health care providers "should make every effort to obtain and administer VariZIG" when indicated.

It can be requested from the sole authorized U.S. distributor, FFF Enterprises (Temecula, Calif.), through its 24-hour telephone line, 800-843-7477.

The expanded access protocol received central institutional review board approval, meaning that the FDA does not require additional institutional review board approval at individual institutions, according to the CDC.

Pharmacists and health care providers who anticipate needing the product can acquire inventory in advance, and, as with any product used under an investigational new drug application, patients must be informed of its potential risks and benefits and must give their informed consent before using it.

Patients receiving the therapy should be observed closely for 28 days after exposure for signs and symptoms of varicella (VariZIG might prolong the incubation period by 1 week or more) and treated with acyclovir antiviral therapy if necessary.

When varicella vaccine is not contraindicated, patients receiving VariZIG should be subsequently vaccinated but only after a delay of 5 months. Vaccination is not necessary if the patient contracts varicella after receiving VariZIG.

If VariZIG is not available within 96 hours of exposure, a single intravenous dose of immune globulin should be considered as an alternative, at a recommended dose of 400 mg/kg, administered once. ■

Injectable Cefazolin Recalled Due to Possible Microbial Contamination

Hanford Pharmaceuticals Inc. is recalling four lots of cefazolin for injection due to the possibility of microbial contamination, which may pose a serious or life-threatening risk for some patients.

The recall affects 379,975 vials (1 g/10 mL) in lots distributed by Sandoz Inc. (C4650 and C4537) and Watson Pharmaceuticals Inc. (C4689 and C4665).

Certain lots of the active ingredient used to manufacture the product have been shown to contain microbial contamination, including *Bacillus pumilus*, *Staphylococcus hominis*, *Propionibacterium acnes*, and *Micrococcus luteus*.

Cefazolin injection is used to treat skin and skin structure, respiratory, and other infections. Users, hospitals, and clinics should stop using the affected lots immediately.

Patients who believe that they may have experienced an adverse reaction to the recalled product are advised to seek medical help.

For more information, contact the company by calling 315-476-7418. Adverse reactions experienced by users of this product should also be reported to the Food and Drug Administration's MedWatch Program at www.fda.gov/medwatch/report.htm or 800-332-1088.

—Kerri Wachter

Avian Flu Spreads to Second Sub-Saharan Country's Birds

BY KATE JOHNSON
Montreal Bureau

The spread of avian influenza to poultry in Niger confirms officials' fears that conditions in West Africa favor further spread of the infection, the World Health Organization has reported.

There are currently no human cases of H5N1 viral infection confirmed in Africa. In Nigeria, local tests have ruled out avian influenza in three of four people with respiratory illnesses, one of which was fatal.

Spread of the virus to additional parts of Africa could broaden opportunities for human cases to emerge under circumstances where capacities are limited.

Concern about the potential for human infection remains high, the World Health Organization (WHO) said in a statement. "The WHO is concerned that spread of the virus to additional parts of Africa will broaden opportunities for human cases to occur under circumstances where capacities to find, diagnose, investigate, and manage cases are limited," the organization said.

Poultry outbreaks in "numerous" other African countries are under investigation, but "throughout most of Africa, rapid detection and investigation of outbreaks are hampered by the absence of an early warning system for avian influenza in animals or humans, inadequate diagnostic capacity, and difficulties in shipping specimens, both internally and abroad, for diagnostic confirmation," the WHO said.

In addition, economic concerns are mounting. "Backyard producers in many developing countries are losing income and are facing increased livelihood and food security risks," the Food and Agriculture Organization (FAO) of the United Nations reported. Globally, more than 200 million chickens have been culled since the onset of the avian influenza crisis, it said in a statement.

The WHO stressed that despite a rapid increase in disease activity among birds and the infection of 174 people (including 94 deaths), proper cooking of poultry products kills the virus. No human cases have been "linked to the consumption of properly cooked poultry or poultry products," the statement said. The FAO confirmed that poultry products cooked at or above 70°C are safe.

Meanwhile, as Sweden joined the list of European countries confirming H5N1 infection in wild birds, German authorities announced the detection of the virus in a dead domestic cat from the island of Ruegen, where the infection has already been confirmed in wild birds. The cat's infection marks the first evidence of avian influenza in a European mammal, but "there is no present evidence that domestic cats play a role in the transmission," said the WHO. "All available evidence indicates that cat infections occur in association with H5N1 outbreaks in domestic or wild birds."

Since 2003 there have been anecdotal reports from Southeast Asia of domestic cat infections with the H5N1 virus. Eating raw infected poultry was the most likely source of those infections, said the WHO. ■

Adult Tdap Safe for Children 18 Months After Previous Vaccine

The adult formula of the tetanus and diphtheria toxoids and acellular pertussis vaccine (Tdap) can be given to children and adolescents starting at 18 months after a children's formula tetanus and diphtheria vaccine, said Dr. Scott A. Halperin of Dalhousie University, Halifax, Nova Scotia, and his colleagues.

Prior recommendations for a 10-year waiting period between doses of the tetanus and diphtheria toxoid–containing vaccine for infants and young children (TD) or the vaccine for older children and adults (Td) had been based on effectiveness rather than a lack of safety information, the investigators noted.

Concerns about the timing of vaccinations and adverse events prompted an open-label clinical trial including 7,156 children in grades 3-12 who received Tdap at time intervals ranging from 18 months to 9 years after their previous vaccinations with TD, Td, or diphtheria-tetanus-acellular pertussis (DTaP).

Tdap was generally well tolerated regardless of the time elapsed since the previous vaccination. Data on fever, injection site erythema, swelling, and pain were solicited for 14 days after immunization, and unsolicited adverse events were recorded for 28 days (Pediatr. Infect. Dis. J. 2006;25:195-200).

Overall, more than 80% of the children in each time interval reported injection site pain, but this was not significantly different from pain reports in children who were vaccinated 10 years after a previous immunization. Injection site erythema was slightly increased among children whose previous vaccine had been DTaP, but not among those whose previous vaccine had been Td. The four reported serious adverse events included one case each of asthma, bronchospasm, syncope, and juvenile onset diabetes mellitus, but none of these were attributed to Tdap.

—Heidi Splete