Canada to Supply Varicella Postexposure Prophylaxis

BY KATE JOHNSON
Montreal Bureau

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.

Pharmacists and health care providers can acquire inventory of the product in advance; patients must be informed of its potential risks and give informed consent.

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[earlyrelease]: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 (IND) 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 dose of immune globulin intravenous should be considered as an alternative, at a recommended dose of 400 mg/kg, administered once. ■

Injection Prevents Complications

Oxytocin *from page 1*

minutes in the oxytocin group), but significantly more women in the saline group than in the oxytocin group had a retained placenta after 15 minutes (5 vs. 0 women).

Furthermore, the groups had similar mean hemoglobin levels prior to delivery (11.7 vs. 12.1 g/dL), but those who received saline had significantly lower mean postpartum hemoglobin levels (used as a measure of blood loss) than did those in the oxytocin group (9.9 vs. 10.8 g/dL), said Dr. Ghulmiyyah of the University of Cincinnati.

Patients in both groups were treated via intraumbilical vein injection, with injection performed slowly over 1 minute following cord clamp.

Although audience members debated the value of routine use of oxytocin for preventing placental retention—with at least one saying it could provide a clinical and practical solution to an important problem, and others arguing that more safety and cost-benefit data are needed—Dr. Ghulmiyyah said that he would recommend its routine use, particularly in patients who present in active labor with no intravenous access, and in patients such as Jehovah's Witnesses, for whom blood transfusion would not be an option.

The technique is simple and inexpensive, and no maternal complications occurred in this or prior studies of oxytocin use for placental retention, he said. ■

Bleeding, Pathogens Combined Increase Risk of Preterm Birth

BY SHARON WORCESTER
Southeast Bureau

Miami Beach — Unexplained vaginal bleeding and fetal exposure to oral pathogens have been linked individually with spontaneous preterm birth, and new data suggest the presence of both is associated with greater risk than either alone.

Of 660 pregnancies analyzed, 229 (35%) demonstrated fetal exposure to oral pathogens. Pregnancies that demonstrated such exposure were more likely to be in white women, women who had symptomatic bacterial vaginosis, and women who experienced vaginal bleeding, which was the most significant variable associated with oral pathogen exposure (adjusted risk ratio 1.6).

A total of 51 women (8%) in this planned secondary analysis of the Oral Conditions and Pregnancy Study—a prospective observational study of oral health and pregnancy outcomes—delivered before 35 weeks' gestation, Dr. Kim Boggess reported at the annual meeting of the Society for Maternal-Fetal Medicine.

When women with vaginal bleeding were stratified according to whether fetal exposure to oral pathogens occurred, preterm birthrates were significantly higher in those with both factors. Preterm birth occurred in 30% of those with both factors, compared with 8% in those with only vaginal bleeding, 9% of those with only oral pathogen exposure, and 6% of those with neither.

After adjustment for age, race, prior preterm birth, prior elective or spontaneous abortion, bacterial vaginosis, and enrollment weight, the differences remained. The adjusted hazard ratio for spontaneous preterm birth, compared with those with neither risk factor, was 6.4 for those with both factors, 1.9 for those with only vaginal bleeding, and 2.0 for those with only exposure to oral pathogens, said Dr. Boggess of the University of North Carolina at Chapel Hill.

Fetal exposure to oral pathogens was considered to have occurred if umbilical cord serum at delivery demonstrated an immunoglobulin M–positive (IgM-positive) response to at least one of five oral pathogens, she explained.

"Our findings show that antepartum vaginal bleeding is associated with fetal exposure to oral pathogens, and that the combination of fetal exposure to oral pathogens and vaginal bleeding provides the highest risk for premature birth at less than 35 weeks," Dr. Boggess said.

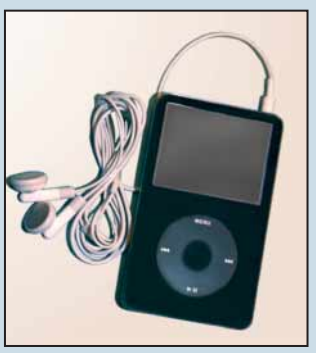
"We think that vaginal bleeding may in fact be an effect measure modifier of fetal exposure to oral pathogens."

Unexplained vaginal bleeding may be one of the mechanisms of fetal exposure to oral pathogens during pregnancy, but further study is needed to determine whether vaginal bleeding is the cause or the effect of fetal exposure to oral pathogens, she said.

The findings also suggest that clinical determination of periodontal disease is a poor marker for fetal exposure to oral pathogens, she noted. ■

Win a Video-Capable iPod!

It's time again for our annual Clinical Pearls contest. This year we are awarding video-capable iPods to six lucky winners. Bruce L. Flamm, M.D., will select the top six entries, which will be featured in upcoming columns.



Ways to Submit Your Entry

1. Drop off your pearls at the Ob.Gyn. News booth #1848 at the annual meeting of the American College of Obstetricians and Gynecologists in Washington, D.C., May 8-10.

2. Send them to Dr. Flamm by

Fax: 909-353-5625
E-mail: bruceflamm@aol.com
Regular mail: Bruce L. Flamm, M.D.
Department of Obstetrics and Gynecology
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Riverside, CA 92505

Multiple submissions are permitted. Dr. Flamm will select what he considers to be the six most clinically useful and concisely presented pearls. All decisions are final. The prize-winning pearls will be published in Dr. Flamm's Clinical Pearls column beginning in the July 15, 2006, issue of Ob.Gyn. News. Other submissions may be published in subsequent columns.
All entries must be received by May 15, 2006.

Visit Dr. Flamm at our booth at the ACOG annual meeting in Washington, D.C.
Where: Exhibit Hall, Ob.Gyn. News Booth #1848
When: Monday, May 8, 11:00 a.m. to 12:00 p.m.
Tuesday, May 9, 11:00 a.m. to 12:00 p.m.