



STATE OF HAWAII
DEPARTMENT OF HEALTH
P.O. Box 3378
HONOLULU, HAWAII 96801-3378

In reply, please refer to:

File:

September 17, 2009

MEDICAL ADVISORY NOTICE:

Alternative Treatment Regimen for Ophthalmia Neonatorum or Neonatal Conjunctivitis During Erythromycin Ophthalmic Ointment Shortage

This Medical Advisory Notice provides information on prevention of ophthalmia neonatorum or neonatal conjunctivitis during the current shortage of erythromycin ophthalmic ointment and on the waiver to the related Hawaii Revised Statutes.

Hawai'i Administrative Rules (HAR) Section 11-156-4.4(b), contains a requirement for either: 1) one percent silver nitrate; or 2) ophthalmic ointments containing tetracycline or erythromycin to be administered to newborns within one hour after birth as prophylaxis for acute infectious conjunctivitis of the newborn. The recent shortage of erythromycin ophthalmic ointment has resulted in some practitioners, hospitals and birthing facilities depleting their supplies of this product and others having only a limited supply. Additionally, tetracycline ophthalmic ointment and silver nitrate solution are no longer manufactured or available for purchase in the United States.

On September 17, 2009, Chiyome Leinaala Fukino, M.D., Director of Health, granted a waiver to HAR §11-16-4.4(b) to allow for use of alternative regimens recommended by the Centers for Disease Control (CDC) [authorized ONLY where erythromycin ophthalmic ointment is unavailable]:

Alternatives if erythromycin (0.5 percent) ophthalmic ointment is unavailable

1. AzaSite® (azithromycin ophthalmic solution, one percent, Inspire Pharmaceuticals) is the current CDC-recommended substitute. DOH has confirmed that this is currently in stock.

Recommended dose is one to two drops placed in the conjunctival sac of each eye. Because this is a solution, rather than an ointment, it is important that drops are placed properly. Consider a two-person administration approach: one to hold the eyelids open, and the other to administer the medication. Use is recommended whether the infant is delivered vaginally or by cesarean section.

Acceptable alternatives, according to the CDC, when both ophthalmic ointment and azithromycin ophthalmic solution are not available include: Gentak® (Gentamicin ophthalmic ointment, 0.3 percent, Akorn) or Tobrex® (tobramycin ophthalmic ointment 0.3 percent, Alcon Laboratories). Betadine (povidine iodine) is not recommended.

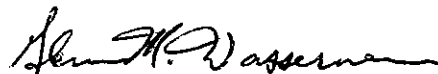
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Since efficacy data are not available for any of the alternate regimens, providers should be alert to the possibility of failure of prophylaxis and should follow the American Academy of Pediatrics' recommendation that infants be seen for their first post-natal office visit 48 to 72 hours post-discharge from the hospital. At this visit, examine closely for ophthalmia neonatorum. Testing for *Neisseria gonorrhoeae* should be included for all infants with ophthalmia neonatorum and reports of prophylaxis failure sent to DOH and to CDC.

If none of the above-referenced alternatives are available, the CDC lists a third alternative approach, for mothers to be tested for chlamydia and gonorrhea prior to delivery, and results obtained as soon as possible. The 2006 STD Treatment Guidelines outlines recommended prophylactic treatment for infants whose mothers have gonococcal infection and for management of infants born to mothers who have untreated chlamydia. Empiric treatment is recommended for infants exposed to gonorrhea, while monitoring for development of symptoms prior to initiating treatment is recommended for infants exposed to chlamydia. See <http://www.cdc.gov/std/treatment/2006/erythromycinOintmentShortage.htm>.

You are strongly encouraged to monitor CDC's website, <http://www.cdc.gov/std/treatment/>, for up to date information and alternatives caused by this temporary shortage of erythromycin (0.5%) ophthalmic ointment. If you have questions or need additional information, please contact Ms. Venie Lee, Disease Investigation Services Supervisor, at the DOH STD/AIDS Prevention Branch at venie.lee@doh.hawaii.gov or (808) 733-9281, or me, Dr. Glenn Wasserman at glenn.wasserman@doh.hawaii.gov or (808) 586-4580. Thank you.

Sincerely,



Glenn M. Wasserman, M.D., M.P.H.
Chief, Communicable Disease Division
Hawaii Department of Health