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Emergency Regulation Change Regarding Prophylactic Treatment of Newborns' Eyes

Background

Ophthalmia neonatorum is defined as conjunctivitis occurring within the first 4 weeks of life. While there are many causes of ophthalmia neonatorum, *Neisseria gonorrhoeae* is most commonly associated with more severe disease. As is true in most states, Alaska law requires that a prophylactic agent be instilled into the eyes of all newborn infants to prevent gonococcal ophthalmia neonatorum. Erythromycin (0.5%) ophthalmic ointment is the recommended prophylactic treatment of choice.

On August 31, 2009, the Centers for Disease Control and Prevention (CDC) indicated that there is a national shortage of erythromycin (0.5%) ophthalmic ointment. According to CDC, the shortage is due to a change in manufacturers. Fera Pharmaceuticals, which recently acquired the rights to erythromycin (0.5%) ophthalmic ointment, and Bausch & Lomb, which also manufactures the product, are working with the Food and Drug Administration (FDA) to increase production and supply. Guidelines for securing existing supplies and alternative treatment guidelines for providers unable to obtain an adequate supply are available online.^{1,2}

Emergency Regulation Change

Alaska regulation 7 AAC 27.111 regarding the prophylactic treatment of newborns' eyes was adopted in 1980,³ and allowed for the use of three medications: 1% silver nitrate ophthalmic solution, tetracycline ophthalmic ointment, and erythromycin (0.5%) ophthalmic ointment. The first two medications are no longer available commercially in pediatric dosages in the United States.

On September 18, 2009, the Alaska Department of Health and Social Services (DHSS) adopted, as an emergency regulation, changes to 7 AAC 27.111 (Box).⁴ These changes were needed in order to allow DHSS to adopt the recommended alternative medications listed by the CDC for the prophylactic treatment of newborns' eyes and to eliminate recommendations for the use of alternative regimens that are no longer available in pediatric dosages in the United States.

Box. Emergency Regulation Changes to 7 AAC 27.111. Prophylactic Treatment of Newborns' Eyes

- (a) Each infant born in the state must have administered to the infant by a physician, nurse or certified direct – entry midwife, one of the following prophylactic measures within two hours after birth onto the inside of the infant's lower eyelids:
- (1) [one-percent silver nitrate solution dispensed from individual wax ampoules and allowed to remain in place without irrigation] (repealed)
 - (2) [tetracycline ophthalmic ointment;] (repealed)
 - (3) erythromycin ophthalmic ointment ; or
 - (4) a department-approved alternative prophylactic ophthalmic agent as recommended by the Centers for Disease Control and Prevention for the prevention of ophthalmia neonatorum in the newborn. (added)

(Note: Sections 111(b) and 111(c) of this regulation were not changed and are not shown here.)

Discussion

The updated CDC recommendations for prevention of ophthalmia neonatorum include medications that are not FDA-approved. These medications are recommended on the basis of available data on pharmacology and gonococcal microbiologic sensitivity, but no data exist regarding the efficacy of these products for the prophylactic treatment of ophthalmia neonatorum.²

In addition to routine newborn prophylaxis, the 2006 *STD Treatment Guidelines* outline recommended prophylactic treatment for infants whose mothers have gonococcal infection and for management of infants born to mothers who have untreated chlamydia.⁵ 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.^{2,5}

DHSS intends to make the emergency changes to 7 AAC 27.111 permanent on January 15, 2010, following a public comment period ending October 23, 2009 at 5:00 PM. Instructions for submission of public comment can be found at the DHSS website.⁴

Recommendations

1. Providers should review their supplies of erythromycin ophthalmic ointment (0.5%) routinely and reserve current supplies for neonatal prophylaxis use. For normal replacement supplies, contact the wholesale distributor directly. For severely low supplies (i.e., depletion within a week), contact the wholesale distributor or call Bausch & Lomb customer service at 1-800-323-0000 directly.
2. When erythromycin (0.5%) ophthalmic ointment is not available, AzaSite® (Azithromycin Ophthalmic Solution 1%, Inspire Pharmaceuticals) is an acceptable alternative.
3. If neither AzaSite® nor Erythromycin Ophthalmic Ointment (0.5%) is available, the following are acceptable alternatives: Gentak® (Gentamicin Ophthalmic Ointment 0.3%, Akorn) or Tobrex® (Tobramycin Ophthalmic Ointment 0.3%, Alcon Laboratories).
4. If none of the above preparations are available, a fluoroquinolone ophthalmic ointment: Ciloxan® (Ciprofloxacin Ophthalmic Ointment 0.3%, Alcon Laboratories) can be used, but this is a less suitable alternative given data on possible gonococcal antimicrobial resistance.
5. Betadine (povidone iodine) is not recommended due to the potential confusion with and possible use of the more familiar detergent formulation, which can be harmful.
6. Providers should be alert to the possibility of failure of prophylaxis.²

References

1. U.S. Food and Drug Administration FDA Drug Shortages. Available at: <http://www.fda.gov/Drugs/DrugSafety/DrugShortages>
2. Centers for Disease Control and Prevention Guidance on Shortage of Erythromycin (0.5%) Ophthalmic Ointment – September 2009. Available at: <http://www.cdc.gov/std/treatment/2006/erythromycinOintmentShortage.htm>
3. 7 AAC 27.111. Prophylactic treatment of newborns' eyes. Available at: <http://touchngo.com/iglcnt/akstats/aac/title07/chapter027/section111.htm>
4. State of Alaska Department of Health and Social Services, Proposed Regulation Change. Available at: <http://www.hss.state.ak.us/apps/publicnotice/RegulationDetails.aspx?Regulation=b02f8ee9-3ec0-4bfd-81eb-e5121a8e06f9>
5. Centers for Disease Control and Prevention, 2006 *STD Treatment Guidelines*. Available at: www.cdc.gov/std/treatment