Alaska Public Health Advisory

March 15, 2019

STD Drug Shortages – Erythromycin, Ceftriaxone Diluents & Penicillin G

The purpose of this health alert network message is to notify providers about STD drug shortages and provide an update on the previous shortage of Penicillin G.

The Centers for Disease Control and Prevention (CDC) request information on any challenges providers encounter in procuring the products in this public health advisory. If you experience any difficulties, please notify Tracy Smith, Alaska STD Coordinator, Section of Epidemiology, at 907-269-8087 or 907-269-8000.

Erythromycin (0.5%) Ophthalmic Ointment Shortage

On March 5, 2019, the Food and Drug Administration (FDA) released a report on a **shortage of erythromycin (0.5%) ophthalmic ointment**. This is a serious problem for a number of reasons. Erythromycin (0.5%) ophthalmic ointment is the only antibiotic ointment currently recommended and the only drug cleared by the FDA for the prophylaxis of gonococcal ophthalmia neonatorum. Furthermore, gonorrhea ocular prophylaxis of newborns is mandated by law in most states and is considered standard neonatal care. This prophylaxis was recently reaffirmed by the <u>USPSTF</u>.

If erythromycin ointment is not available, CDC recommends that neonates at risk for exposure to *N. gonorrhoeae* during delivery (especially those born to a mother at risk for gonococcal infection or with no prenatal care) be administered ceftriaxone 25–50 mg/kg IV or IM, not to exceed 125 mg in a single dose. For more information about medications substitutes for erythromycin ointment, please see the 2015 STD Treatment Guidelines and if questions, please contact Tracy Smith at 907-269-8087 or 907-269-8000, or Roxanne Barrow, MD, MPH, Medical Epidemiologist, (rbarrow@cdc.gov; 404-639-8503).

Other topical medications are not recommended:

- Tetracycline ophthalmic ointment and silver nitrate are no longer available in the United States;
- Gentamicin was associated with chemical conjunctivitis during the last erythromycin shortage;
- Povidone-iodine has limited data on its benefits and harms.

It is important to remember that prenatal screening is the best method for preventing gonococcal ophthalmia neonatorum among newborns! All pregnant women < 25 years of age and pregnant women ≥ 25 at increased risk should be screened for *N. gonorrhoeae* at the first prenatal care

visit and again in the third trimester if risk continues during pregnancy. Also, the CDC recommends that all females, regardless of pregnancy status, who have been treated for gonorrhea should be retested 3 months after treatment.

Current information regarding the availability of erythromycin (0.5%) ophthalmic ointment is available at the <u>FDA Drug Shortage Website</u>.

Ceftriaxone Diluents Update

Diluents for Ceftriaxone are in limited supply. Ceftriaxone is the last remaining known effective antimicrobial for the treatment of uncomplicated gonorrhea and dual therapy with azithromycin has been recommended to mitigate the emergence of ceftriaxone resistance in the United States. The usual preparation for ceftriaxone is a powder form reconstituted with an appropriate diluent. One percent lidocaine without epinephrine is the preferred diluent to use by most STD clinical experts in an effort to minimize significant patient discomfort from the intramuscular injection. The full product insert for ceftriaxone lists other diluents for consideration. The FDA continues to work closely with manufacturers and to update their website related to the availability of all of the diluents.

Diluents currently in shortage: <u>1% lidocaine without epinephrine</u>, <u>sterile water</u>, and <u>0.9%</u> sodium chloride

Again CDC is interested in hearing about any shortages of 1% lidocaine without epinephrine or if any provider who cannot procure diluents at all and is not treating gonorrhea patients with ceftriaxone as a result. Please report any challenges in procurement of the product to Tracy Smith, Section of Epidemiology, at 907-269-8087 and we will relay this information to CDC.

UPDATE: Penicillin G benzathine (Bicillin L-A®) and Penicillin G procaine Update

There is good news related to the supply of Penicillin G benzathine (Bicillin L-A®) and Penicillin G procaine in the United States. After a protracted shortage, Penicillin G benzathine (Bicillin L-A®) is back to normal supply levels and has been moved by the FDA to a resolved shortage status.

As supply can be fragile when there is only one manufacturer and Penicillin G benzathine is the only recommended treatment for syphilis in adults in the <u>2015 CDC STD Treatment Guidelines</u> we encourage the following:

Note: Doxycycline is an alternative treatment for non-pregnant patients and only if a
medical contraindication exists such as an IgE mediated allergy to penicillin. Efficacy
of doxycycline has not been well-studied, is considered inferior to penicillin and if
utilized, close laboratory and clinical follow-up of the patient is indicated.

- Please report to Tracy Smith, State STD Program Coordinator at 907-269-8087:
 - o If a patient is unable to afford Penicillin G benzathine (Bicillin L-A®) out of pocket or because of co-pays, or
 - If health care providers or pharmacies have any difficulty in procuring Penicillin
 G benzathine product, we will report this to CDC.
- Clinicians with questions about STD clinical management can contact the online National Network of STD Clinical Prevention Training Centers (NNPTC) STD Clinical Consultation Network at https://www.stdccn.org.

After an even more protracted shortage, **Penicillin G procaine is now available at normal supply levels and the FDA has recently moved it to the resolved shortage status.** Penicillin G procaine is an alternative regimen for outpatient treatment of neurosyphilis and congenital syphilis.

Resources:

- 1. Centers for Disease Control and Prevention. <u>2015 STD Treatment Guidelines</u>. https://www.cdc.gov/std/tg2015/default.htm
- 2. Centers for Disease Control and Prevention: Procaine Penicillin G Shortage. https://www.cdc.gov/std/treatment/drugnotices/procaine-peng.htm
- 3. FDA Drug Shortages.

 https://www.accessdata.fda.gov/scripts/drugshortages/dsp ActiveIngredientDetails.cfm?AI =Penicillin%20G%20Procaine%20Injection&st=r&tab=tabs-1