



North Carolina Department of Health and Human Services
Division of Public Health • Epidemiology Section
Communicable Disease Branch

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Beverly Eaves Perdue, Governor
Lanier M. Cansler, Secretary

Jeffrey P. Engel, MD
State Health Director

Memo

To: Local Health Directors
Local Nursing Directors

From: Peter Leone, MD

Date: May 20, 2010

Re: Ceftriaxone Shortage

We want to inform you of a developing situation in North Carolina. We have a shortage of ceftriaxone. Ceftriaxone (trade name Rocephin) is a sterile, semisynthetic, broad-spectrum cephalosporin antibiotic given in our clinics as an intramuscular injection and is our first-line for treatment of Gonorrhea. Our supplier is Cardinal Pharmacy who states the supply shortage is due to manufacturing production issues. What is not clear is whether this is a local problem or an emerging national one. There are apparently five manufactures for the drug in the US. They include but not limited to Roche, Sandoz, and Lupin. We have been informed the supply shortage should be of a limited time, but since we do not know the extent of the problem I am providing recommendations on alternative options for treatment.

Alternative regimens for uncomplicated gonococcal infection in adults include:

Cefixime 400 mg as a single oral dose

Or

Azithromycin 2.0 g as a single oral dose

Several caveats should be considered with alternative therapies: A cefixime 400 mg oral dose does not provide as high, nor as sustained, a bactericidal level as that provided by the 250 mg dose of ceftriaxone. In published clinical trials, the 400 mg dose cured 97.5% of uncomplicated urogenital and anorectal (lower 95% confidence interval (CI) = 95.4%) and 92.3% of pharyngeal gonococcal infections (lower 95% CI = 74.9%). The advantage of cefixime is that it can be administered orally;



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however, ceftriaxone should be used if pharyngeal infection is suspected. Single-dose injectible cephalosporin regimens (other than ceftriaxone 250 mg IM) that are safe and highly effective against uncomplicated urogenital and anorectal gonococcal infections include ceftizoxime (500 mg, administered IM), cefoxitin (2 g, administered IM with probenecid 1 g orally), and cefotaxime (500 mg, administered IM). None of the injectible cephalosporins offer any advantage over ceftriaxone for urogenital infection, and efficacy at the pharynx is less certain.

Azithromycin 2 g orally is effective against uncomplicated gonococcal infection (efficacy 99.2%, CI=97.3%-99.9%), but concerns over the ease with which *N. gonorrhoeae* can develop resistance to macrolides should restrict its use to limited circumstances. Although azithromycin 1g theoretically meets alternative regimen criteria (efficacy 97.6%, CI=95.7%-98.9%), it is not recommended because several studies have documented treatment failures with that regimen and because this dose raises even greater concerns about possible rapid emergence of antimicrobial resistance than does the 2 g dose of azithromycin. *N. gonorrhoeae* in the United States is not adequately susceptible to penicillins, tetracyclines, and older macrolides (e.g., erythromycin) for these antimicrobials to be recommended.

Please contact Kristen Hancock @ 919-733-2030 ext 204 if you either have a shortage of ceftriaxone on site (less than an estimated 60 day supply) or if you have an excess of supply (greater than an estimated 90 day supply). See attached new STD Drug order form. We will work with our Local Health Departments to redistribute supplies should this be necessary.