

CDC Finds First Cluster of Highly Resistant Gonorrhea in US

Megan Brooks | September 22, 2016

Health officials have identified the first cluster of gonorrhea infections in the United States to show decreased susceptibility to ceftriaxone and very high-level resistance to azithromycin — the last line of defense against the sexually transmitted infection.

"Our last line of defense against gonorrhea is weakening," Jonathan Mermin, MD, director of the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention at the Centers for Disease Control and Prevention (CDC), said in a statement. "If resistance continues to increase and spread, current treatment will ultimately fail and 800,000 Americans a year will be at risk for untreatable gonorrhea."

The CDC currently recommends dual therapy with a single shot of ceftriaxone and an oral dose of azithromycin to treat gonorrhea, according to the statement.

Details of the cluster were presented September 21 at the 2016 STD Prevention Conference in Atlanta, Georgia.

"We're seeing new troubling signs that our current gonorrhea treatment may be losing its effectiveness," Dr Mermin said during a press briefing.

But help may be on the way. Researchers at the conference reported promising phase 2 data on a novel experimental oral antibiotic under development, which may offer a new weapon against gonorrhea.

Hawaii Cluster

A joint investigation by the CDC and the Hawaii State Department of Public Health found that eight gonococcal isolates from seven individuals (six males, one female) in Honolulu in April and May of 2016 showed resistance to azithromycin at much higher levels than typically seen in the United States. Isolates from five of these individuals also showed reduced susceptibility to ceftriaxone.

"The Hawaii cluster is concerning, as all eight isolates demonstrated high levels of azithromycin resistance, resistance to penicillin, tetracycline and ciprofloxacin, and five of the eight demonstrated reduced susceptibility to ceftriaxone by agar dilution testing, and the isolates were genetically related," said Alan Katz, MD, MPH, from the Hawaii State Department of Health's Diamond Head STD Clinic.

Dr Mermin noted that the [Hawaii cluster](http://www.cdc.gov/mmwr/volumes/65/ss/ss6507a1.htm) (<http://www.cdc.gov/mmwr/volumes/65/ss/ss6507a1.htm>) is "even more concerning than data CDC published earlier this year that showed evidence of emerging azithromycin resistance across the nation, but those cases were susceptible to ceftriaxone."

"These are the latest signs that the effectiveness of today's treatment may soon be in jeopardy," Dr Mermin warned. He said it's important to note that all the patients in Hawaii who were identified as part of this cluster were successfully treated with ceftriaxone and azithromycin, and no further cases have been identified since May. "But for the current recommended drug combination, the findings are also a red flag. If resistance continues to increase and spread, our current treatment regimen will eventually fail."

To date, no confirmed failures of the CDC-recommended dual therapy (250 mg ceftriaxone intramuscularly plus 1 g azithromycin) have been reported in the United States.

Novel Antibiotic Shows Promise

Researchers are hopeful that a novel experimental oral antibiotic under development may offer a new weapon against gonorrhea.

In a phase 2 clinical trial supported by the National Institutes of Health, the drug, now known as ETX0914, was generally safe and effective for treatment of uncomplicated urogenital gonorrhea, reported lead investigator Stephanie Taylor, MD, professor of medicine and microbiology at Louisiana State University Health Sciences Center in New Orleans.

ETX0914 is being developed by Entasis Therapeutics. "The thing that's different about this antibiotic, and that we're really pleased with, is that it has a different mechanism of inhibiting DNA synthesis of the organism" from any currently marketed antibiotic, Dr Taylor said.

ETX0914, she further explained, "doesn't count as a fluoroquinolone, although it does interact with DNA gyrase in a different way or in a different location than fluoroquinolone. So, it is completely different from fluoroquinolone." Therefore, if approved, "it would be a brand new class of antibiotics. There are none marketed, none on the market right now with this mechanism of action."

In preclinical testing, ETX0914 was active against strains of gonorrhea that were resistant to other existing classes of drugs. In the phase 2 trial, researchers treated 167 men and 12 women for gonorrhea using ETX0914 alone (at 2-g or 3-g dosage levels) or 500 mg ceftriaxone alone. The primary endpoint was eradication of the organism, which was measured by negative cultures for gonorrhea at the test-of-cure visit.

All patients in the 3-g ETX0914 group (47 of 47) and 98% of patients in the 2-g group (48 of 49) were cured. A total of 21 patients who received ETX0914 (11.7%) reported side effects, mostly mild gastrointestinal issues.

"We are very encouraged by these results, and we look forward to this study drug moving on to further clinical trials," Dr Taylor said.

ETX0914 has been designated a Qualified Infectious Disease Product by the US Food and Drug Administration and awarded a [fast track status](http://www.businesswire.com/news/home/20160921006046/en/Entasis-Announces-Positive-Phase-2-Data-ETX0914) (<http://www.businesswire.com/news/home/20160921006046/en/Entasis-Announces-Positive-Phase-2-Data-ETX0914>).

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