

## Surge in syphilis cases leads some providers to ration penicillin

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When Stephen Miller left his primary care practice to work in public health a little under two years ago, he said, he was shocked by how many cases of syphilis the clinic was treating.



For decades, rates of the sexually transmitted infection were low. But the Hamilton County Health Department in Chattanooga—a midsize city surrounded by national forests and nestled into the Appalachian foothills of Tennessee—was seeing several syphilis patients a day, Miller said. A nurse who had worked at the clinic for decades told Miller the wave of patients was a radical change from the norm.

What Miller observed in Chattanooga is reflective of a trend that is raising alarm bells for health departments across the country.

Nationwide, syphilis rates are at a 70-year high. The Centers for Disease Control and Prevention said Jan. 30 that 207,255 cases were reported in 2022, continuing a steep increase over five years. Between 2018 and 2022, syphilis rates rose about 80%. The epidemic of sexually transmitted infections—especially syphilis—is "out of control," said the National Coalition of STD Directors.

The surge has been even more pronounced in Tennessee, where infection rates for the first two stages of syphilis grew 86% between 2017 and 2021.

But this already difficult situation was complicated last spring by a shortage of a specific penicillin injection that is the go-to treatment for syphilis. The ongoing shortage is so severe that public health agencies have recommended that providers ration the drug—prioritizing pregnant patients, since it is the only syphilis treatment considered safe for them. Congenital syphilis, which happens when the mom spreads the disease to the fetus, can cause birth defects, miscarriages, and stillbirths.

Across the country, 3,755 cases of congenital syphilis were reported to the CDC in 2022—that's 10 times as high as the number a decade before, the recent data shows. Of those cases, 231 resulted in stillbirth and 51 led to infant death. The number of cases in babies swelled by



183% between 2018 and 2022.

"Lack of timely testing and adequate treatment during pregnancy contributed to 88% of cases of <u>congenital syphilis</u>," said a report from the CDC released in November. "Testing and treatment gaps were present in the majority of cases across all races, ethnicities, and U.S. Census Bureau regions."

Hamilton County's syphilis rates have mirrored the national trend, with an increase in cases for all groups, including infants.

In November, the maternal and infant health advocacy organization March of Dimes released its <u>annual report</u> on states' health outcomes. It found that, nationwide, about 15.5% of pregnant people received care beginning in the fifth month of pregnancy or later—or attended fewer than half the recommended prenatal visits. In Tennessee, the rate was even worse, 17.4%.

But Miller said even those who attend every recommended appointment can run into problems because providers are required to test for syphilis only at the beginning of a pregnancy. The idea is that if you test a few weeks before birth, there is time to treat the infection.

However, that recommendation hinges on whether the provider suspects the patient was exposed to the bacterium that causes syphilis, which may not be obvious for people who say their relationships are monogamous.

"What we found is, a lot of times their partner was not as monogamous, and they were bringing it into the relationship," Miller said.

Even if the patient tested negative initially, they may have contracted syphilis later in pregnancy, when testing for the disease is not routine, he said.



Two antibiotics are used to treat syphilis, the injectable penicillin and an oral drug called doxycycline.

Patients allergic to penicillin are often prescribed the oral antibiotic. But the World Health Organization strongly advises pregnant patients to avoid doxycycline because it can cause severe bone and teeth deformities in the infant.

As a result, pregnant syphilis patients are often given penicillin, even when they're allergic, using a technique called desensitization, said Mark Turrentine, a Houston OB-GYN. Patients are given low doses in a hospital setting to help their bodies get used to the drug and to check for a severe reaction. The penicillin shot is a one-and-done technique, unlike an antibiotic, which requires sticking to a two-week regimen.

"It's tough to take a medication for a long period of time," Turrentine said. The single injection can provide patients and their clinicians peace of mind. "If they don't come back for whatever reason, you're not worried about it," he said.

The Metro Public Health Department in Nashville, Tennessee, began giving all non-pregnant adults with syphilis the oral antibiotic in July, said Laura Varnier, nursing and clinical director.

Turrentine said he started seeing advisories about the injectable penicillin shortage in April, around the time the antibiotic amoxicillin became difficult to find and physicians were using penicillin as a substitute, potentially precipitating the shortage, he said.

The rise in syphilis has created demand for the injection that manufacturer Pfizer can't keep up with, according to the American Society of Health-System Pharmacists. "There is insufficient supply for usual ordering," the ASHP said in a memo.



Even though penicillin has been around a long time, manufacturing it is difficult, largely because so many people are allergic, said Erin Fox, associate chief pharmacy officer for the University of Utah health system and an adjunct professor at the university, who studies drug shortages.

"That means you can't make other drugs on that manufacturing line," she said. Only major manufacturers like Pfizer have the resources to build and operate such a specialized, cordoned-off facility. "It's not necessarily efficient—or necessarily profitable," Fox said.

In a statement, Pfizer confirmed the amoxicillin shortage and surge in syphilis increased demand for injectable penicillin by about 70%. Representatives said the company invested \$38 million in the facility that produces this form of penicillin, hiring more staff and expanding the production line.

"This ramp up will take some time to be felt in the market, as product cycle time is 3-6 months from when product is manufactured to when it is available to be released to customers," the statement reads. The company estimated the shortage would be significantly alleviated by spring.

In the meantime, Miller said, his clinic in Chattanooga is continuing to strategize. Each dose of injectable penicillin can cost hundreds of dollars. Plus, it has to be placed in cold storage, and it expires after 48 months.

Even with the dramatic increase in cases, syphilis is still relatively rare. More than 7 million people live in Tennessee, and in 2019, providers statewide reported 683 cases of syphilis.

Health departments like Miller's treat the bulk of syphilis patients. Many



patients are sent by their provider to the health department, which works with contact tracers to identify and notify sexual partners who might be affected and tests patients for other sexually transmitted infections, including HIV.

"When you diagnose in the office, think of it as just seeing the tip of the iceberg," Miller said. "You need a team of individuals to be able to explore and look at the rest of the iceberg."

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