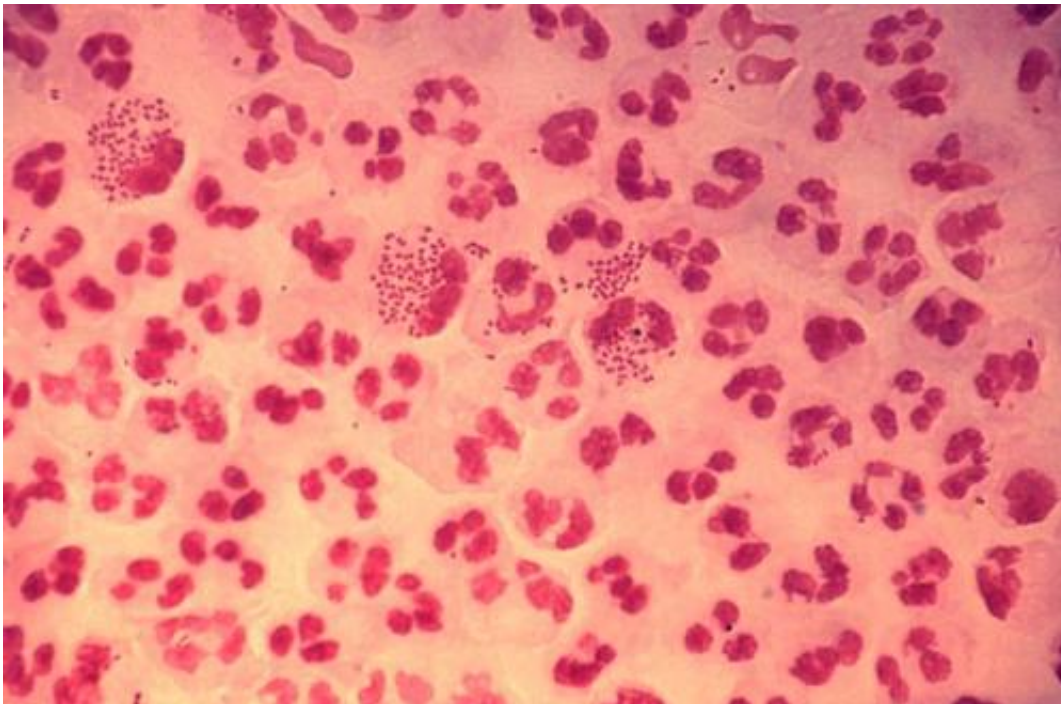


Gonorrhea shot gets FDA fast track as resistant cases multiply

June 29 2023, by Matthew Griffin, Bloomberg News



Credit: CDC

GSK Plc's experimental gonorrhea vaccine got fast-track designation from U.S. regulators, putting the shot in position to become the first preventive for a common, often-undetected infection that's gaining resistance to treatment.

The Food and Drug Administration status makes the drug eligible for a

sped-up approval process, if an ongoing midstage trial shows it's effective, the company said Tuesday. GSK learned of its status in April and plans to move the [vaccine](#) to final-stage testing in 2026, said Giulia Giordano, vaccine development leader for the project.

In 2020, some 82 million people worldwide caught [gonorrhea](#), a [sexually transmitted infection](#) that can lead to complications including infertility. While some patients show early symptoms, such as pain or urethral discharge in men or vaginal discharge in women, many cases may be missed even as the disease does long-term damage.

The situation has been exacerbated by gonorrhea's growing resistance to most antibiotics, and the one that most doctors rely on, ceftriaxone, is now under threat as well. That's left experts clamoring for a vaccine.

"We're very concerned that we are staring straight in the face the prospect of untreatable gonorrhea," said Jeffrey Klausner, who directed sexually transmitted [disease prevention](#) and control for the San Francisco Department of Public Health from 1998 to 2009.

The threat of gonorrhea, along with other sexually transmitted diseases like syphilis and chlamydia, is on the rise around the world. Cases hit a record high in England last year. In the U.S., the rate of reported infections more than doubled between 2009 and 2021.

While older antibiotics like penicillin were once effective, according to the World Health Organization, all gonorrhea strains are now impervious to one or more of the standard drugs. Ceftriaxone, meanwhile, must be taken by injection, and its days may be numbered.

"There is this huge unmet medical need" for better diagnostics and treatment, Giordano said in an interview.

Already, there are signs that ceftriaxone may have its limits. In January, Massachusetts [public health officials](#) reported the first U.S. patient infected by a strain showing reduced susceptibility to all recommended gonorrhea therapies.

The same variant had previously been reported in the U.K. and Asia, state health officials said. Although ceftriaxone was able to clear the infections, the state public health commissioner called the new strain a "serious public health concern."

A vaccine, along with new antibiotics and better [diagnostic tests](#), could help combat gonorrhea, according to the Geneva-based World Health Organization. People can also protect themselves from [infection](#) by using condoms during sex, Klausner said, and evidence suggests that the antibiotic doxycycline can serve as a "morning-after pill" for some infections.

Gonorrhea can target multiple parts of the body, including the throat and rectum. GSK is aiming to develop a vaccine that protects all tissues and organs, Giordano said.

Although GSK is still awaiting data on whether its vaccine works, there's reason to believe it may be effective, said Klausner, a professor of medicine and public health at the University of Southern California who isn't involved in its development. The company already has vaccines for meningitis, a disease caused by a related strain of bacteria, and some studies have found that these shots offer a measure of protection against gonorrhea.

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