

Cheap blood test can discriminate between bacterial, viral infections, study finds

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An illustration of E. coli bacteria. Researchers have developed a new blood test for distinguishing bacterial from viral infections, offering a potential tool for guiding the prescription of antibiotics. Credit: C. Bickel / Science Translational Medicine (2016)

Researchers at the Stanford University School of Medicine have made an important breakthrough in their ongoing efforts to develop a diagnostic test that can tell health-care providers whether a patient has a bacterial infection and will benefit from antibiotics.

The study will be published July 6 in *Science Translational Medicine*.

Antibiotics have saved millions of lives and created a world in which complex and lifesaving surgeries are possible. But the overuse of [antibiotics](#) threatens to create a global scourge of antibiotic-resistant bacterial pathogens. Because of this problem, public health experts regularly remind physicians to prescribe antibiotics only for bacterial infections. But too often there's no easy way for doctors to tell whether a patient's illness is bacterial or viral or, sometimes, if there's even any [infection](#) at all.

"A lot of times you can't really tell what kind of infection someone has," said Timothy Sweeney, MD, PhD an engineering research associate with the Stanford Institute for Immunity, Transplantation and Infection and lead author of the paper. "If someone comes into the clinic, a bacterial or a viral infection often look exactly the same."

"The idea to look for a diagnostic [test](#) came from our previous paper in Immunity last year," said assistant professor of medicine Purvesh Khatri, PhD, the senior author. "In that paper, we found a common response by the human immune system to multiple viruses that is distinct from that for bacterial infections. We wondered whether we could exploit that difference to improve the diagnosis of bacterial or viral infections. But we needed a gene signature consisting of far fewer genes for the test to be clinically useful."

Blood test

The team used publicly available patient [gene expression](#) data to pinpoint just seven human genes whose activity changes during an infection; their pattern of activity can distinguish whether an infection is bacterial or viral.

When pathogens infect the cells of the body, the infection sets off a chain reaction involving the immune system that changes the activity, or expression, of hundreds of genes. Gene expression is the process by which cells extract information from genes and render it in the form of either protein or RNA molecules. Cells have the capacity to express more or less of each molecule, creating a pattern of gene expression that changes in response to external influences, including infections.

The seven-gene test is a vast improvement over earlier tests that look at the activity of hundreds of genes, the researchers said. Because so few genes are involved, the new test will be cheaper and faster, while remaining accurate, they said.

A study in Nepal co-authored by assistant professor of medicine Jason Andrews, MD, revealed that only 5 percent of patients who received antibiotics actually needed them, said Khatri. The Nepalese patients got antibiotic treatment because the drug was cheaper than trying to figure out if they actually needed it. "If we really want to make a difference," Khatri said, "our test has to be more cost-effective than the drug itself." That's an important breakpoint, he said, since it could allow health-care systems to use antibiotics appropriately and save money at the same time.

The work is part of a global response to the need to reduce the use of antibiotics, driven in part by President Obama's National Action Plan for Combating Antibiotic-Resistant Bacteria. Today, drug-resistant bacteria cause 2 million illnesses and 23,000 deaths each year in the United States alone, according to the Centers for Disease Control and

Prevention. And, of the 154 million antibiotic prescriptions written in U.S. doctors' offices and emergency departments each year, it's estimated that 1 in 3 are unnecessary. A 2014 review of antimicrobial resistance reported that unless something is done to stop the evolution of antibiotic-resistant bacteria, such so-called superbugs could cost the world \$100 trillion in gross-domestic-product losses by 2050.

Finally, besides promoting the evolution of drug-resistant microbes, antibiotics increase the risk of side effects such as tendon rupture or kidney damage, and can damage gut and other microbiomes that are essential to overall health.

Hurdles ahead

The new gene-expression test for [bacterial infection](#) faces two hurdles before it can be made available to doctors in a few years. First, it must be thoroughly tested in a clinical setting. Until now, the data and test results for this ongoing work have all come from preexisting, online digital data sets of gene expression from patients with different kinds of infections—not from current patients.

The new study tested the seven-gene test on blood samples from 96 critically ill children, using an assay called NanoString, and found that the test was accurate. But it needs to be further validated in larger numbers of patient blood samples, the researchers said.

Second, the test needs to be incorporated into a device that can give a result in an hour or less. The preliminary NanoString version of the [blood test](#) takes four to six hours—too long for people who are seriously ill. In patients who have sepsis, for example, the risk of death goes up by 6 to 8 percent for every hour that antibiotics are delayed, so it's critically important to act quickly.

In someone who is obviously severely ill, said Sweeney, prescribing antibiotics would be the default. But often patients have early bacterial infections and doctors don't yet realize the patient is in danger. The gene expression test could remove doubt in a matter of minutes, allowing doctors to prescribe antibiotics sooner and save lives.

For that reason, Sweeney and Khatri are working with other researchers on a way to engineer the gene expression test to provide results in under an hour. The plan is to combine an 11-gene test they created a few months ago with the more recent seven-gene test. The 11-gene test reveals if the patient has an infection at all. If they do have an infection, the seven-gene test reveals if it is bacterial or viral. Both tests would be run at the same time.

The researchers envision the two tests as a decision tree. "When you put the new seven-gene set together with the 11-gene set, we can make a decision tree that matches how a physician might think about a patient," said Sweeney. "First we ask, 'Is an infection present?' Because some people present with an inflammation, a fever, a high heart rate, but it's not due to an infection. Then we ask, 'If so, what kind?'"

The 18-gene combination test would first be used in hospitals, Sweeney said. It's possible, he said, that an even cheaper test just using the seven genes could be used in outpatient clinics.

More information: "Robust classification of bacterial and viral infections via integrated host gene expression diagnostics," *Science Translational Medicine*, [DOI: 10.1126/scitranslmed.aaf7165](https://doi.org/10.1126/scitranslmed.aaf7165)

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