

EXCUSE VACCINE-DEVELOPER DE-CHU TANG FOR SOUNDING LIKE A DOWNER, BUT PANDEMICS JUST AREN'T WHAT THEY USED TO BE. "WE'VE HAD THREE PANDEMICS IN THE LAST CENTURY," HE SAYS. THE ASIAN FLU PANDEMIC HIT CHINA IN 1957, THEN MOVED INTO THE U.S. AND TOOK 70,000 LIVES, HE EXPLAINS. AND DON'T GET TANG STARTED ON THE 1918 SPANISH FLU. "IT KILLED 20- TO 50-MILLION PEOPLE IN ONE YEAR, INCLUDING MANY AMERICANS," HE SAYS. "AND BACK THEN, THERE WERE NO JET FLIGHTS, AND THE DENSITY OF HUMAN POPULATION WAS A LOT LOWER THAN IT IS NOW."

So what's to stop the avian flu from becoming a global pandemic? Not much. In the last five years, the virus has swept across continental borders spanning Asia, Africa, and Europe, among other regions. More than a dozen countries since 2003 have reported almost 400 cases of avian flu in humans. It sounds grim, but Tang thinks he and his team of Birmingham-based researchers are tackling a critical first step: creating a vaccine for the U.S. to stockpile in the event of an outbreak.

Tang researched dermatology at the University of Alabama at Birmingham, which makes sense when you know that Vaxin, the company he later helped found, specializes in non-invasive vaccines such as skin patches and intranasal vaccines.

Vaxin opened in 1997 on the UAB campus with a staff of three. The company set to work on a seasonal influenza vaccine, and three years later manufactured its first product: an influenza vaccine delivered through skin patch or inhaled through the nose.

Vaxin has since grown to include nine staffers, and is now located in the Innovation Depot in downtown Birmingham, a modern one-story incubator facility that helps young companies grow.

Among Vaxin's other pursuits: developing needlefree vaccines for anthrax, Alzheimer's, and acne. Recently, though, Vaxin's focus has been on knocking out the avian flu virus. About four years ago, the company, along with UAB, landed a \$3.5-million grant from the National Institutes of Health.

The question arose then: Whom do you treat first—the chicken or the person? Vaxin is exploring both. After all, Tang says, animals incubate and spread the virus so treating them would ultimately benefit humans. "If you can vaccinate the birds, then you lessen the transmission to people," he says.

Granted, human infections with avian influenza are rare, and the spread from human to human is rarer still. Most cases involving humans have occurred after direct contact with infected poultry. The virus' effects range from eye infections to pneumonia to death.

Nevertheless, a 2007 report produced jointly by the United Nations and the World Bank predicted, "there will be an influenza pandemic, sooner or later," and called for preparation now to mitigate the disease's potentially devastating impact.

The U.S. has pledged almost \$950 million to international aid groups working to contain avian and pandemic influenza outbreaks, making it the largest single donor to the collaborative international effort.

The issue with most animal vaccines for avian flu is that you have to pin down the birds in order to vaccinate them. Tang says China sends workers out to farms to inject every chicken with the vaccine. "It's very messy and labor intensive. Moreoever, when a person travels from farm to farm, they may spread the virus. You put people at risk," he says.

So Vaxin developed a vaccine that reduces the human touch. With a \$1-million federal grant, the company is testing a drug injected directly into chicken eggs, administered using a fast, automated system. "Instead

BY GIGI DOUBAN
PHOTO BY JASON WALLIS

avian flu cheat sheet>>

Birds | Avian influenza viruses are carried by wild birds worldwide. They occur naturally, and they don't usually make birds sick. But among birds, the viruses are contagious. What do the viruses do? Depends on the strain of the virus. Infection can result in ruffled feathers and low egg production or death.

People | The good news: Most of us are at low risk of infection. These viruses don't usually infect humans. As long as you don't come in contact with infected birds or their secretions or excretions, you need not worry. Even if you come in contact with an infected person, chances are you'll be ok. "The spread of avian influenza viruses from one ill person to another has been reported very rarely," the CDC says. The bad news: All influenza viruses can mutate, and scientists fear that the avian flu virus one day could spread easily from one person to another. Because these viruses don't commonly infect humans, we have very little immune protection against them. If the avian influenza virus were to spread easily among people, we could see a worldwide outbreak of the disease.

Avian influenza symptoms | These range, but look for typical flu-like *symptoms*: fever, cough, sore throat, and muscle aches. The virus can also cause eye infections, pneumonia, and severe respiratory disease.

of injecting each bird after it's hatched, we can vaccinate 70,000 to 80,000 eggs an hour," Tang says. Most importantly, Vaxin's vaccine does not kill the chicken embryo, nor does it grow the vaccine in eggs as other labs do.

It makes its vaccine in cell culture. "That allows you to do it much more quickly and much more reliably because you don't have to worry about huge flocks of chickens and all the quality control and contamination issues

that are associated with eggs," says Bill Enright, Vaxin's CEO.

Creating a vaccine quickly becomes even more important during a pandemic. "In the event of a pandemic, the longer it takes you to get a vaccine made, the more people die," adds Enright.

Of course, vaccinating animals raises a concern over food safety, as these animals would eventually enter the food chain. (One of the reasons animals aren't vaccinated in the U.S. for avian flu is that with current vaccines, there's no way to tell infected animals from vaccinated ones-Enright says that with Vaxin's vaccine, a quick diagnostic test can distinguish the two.)

So will vaccinated chickens be safe to

three-year grant.

Clinical trials at Vaxin for the intranasal human vaccine will wrap up sometime in 2009. There is only one human vaccine for avian flu in the U.S., approved in 2007 by the

> Food and Drug Administration. It's given via intramuscular injection, and the federal government has purchased the vaccine for stockpile.

> Enright hopes Vaxin's influenza vaccine will be part of a new generation of vaccines. He says Vaxin's intranasal vaccine makes

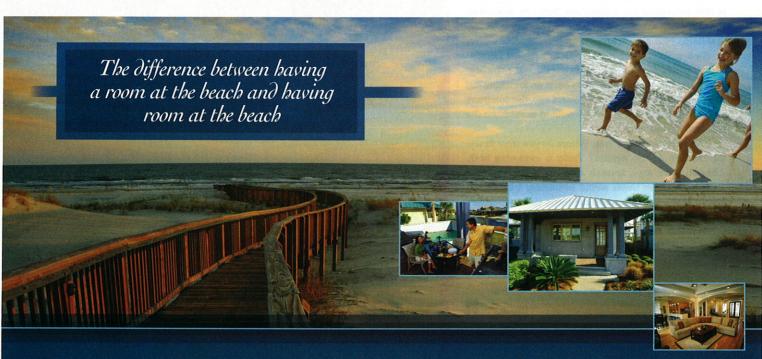
it something people can easily administer themselves. "If there was a pandemic today in the U.S., 300 million people would be lining up at their doctor to get a shot," he says. "Then six weeks later, they'd have to go back to get a second shot. Ideally what we'd like to see is that the pandemic flu vaccine would be part of the seasonal flu vaccine that everybody gets every year." Enright can't yet say how much the vaccine would cost. "That's to be determined," he says. "We believe we can make this cost-effectively."

"From time to time, the influenza virus emerges and changes into a serial killer."

DE-CHU TANG

eat? Enright says they will be. "There's nothing in our vaccine that isn't already in nature, so we don't believe it will have any impact on the food chain."

Vaxin's avian flu vaccine contains human adenovirus, a frequent cause of upper respiratory infections. That virus doesn't persist in chickens, but instead elicits an immunoresponse before the chicken's immune system clears it out. Just how long the entire cycle takes to complete in chickens is something Vaxin hopes to know by the end of the



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