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A better flu vaccine: FluGen strives to make it more effective, plus pain-free

BY **LIZ MERFELD** SEPTEMBER 27, 2012 2:00 PM



FluGen's work may change the way people are vaccinated.

When it comes to the annual flu shot, are you in the better-safe-than-sorry camp or of the "aches and chills build character" persuasion? Either way, you should be interested

in a local company that's working to make a seasonal influenza vaccine that you'd possibly not need to take every year, and that might not hurt a bit.

FluGen, founded in 2007 by Dr. Yoshihiro Kawaoka, Dr. Gabriele Neumann and Paul V. Radspinner, aims to prevent and treat both seasonal and pandemic influenza, and market its intradermal (within the skin) delivery device. In his University Research Park office, Radspinner, the CEO, gives the upshot on their progress on both fronts.

To explain why FluGen's vaccine-in-development, dubbed REDEE FLU, would be superior to what's out there, Radspinner starts with a Biology 101 review. The flu vaccine at your clinic, he explains, is a dead, or "inactivated," vaccine - not to mention that it's grown inside fertilized chicken eggs, a slow and antiquated process FluGen rejects in favor of cell cultures. The vaccine is made of a virus that's been chopped up and destroyed with chemicals; your body sees it as "bits and pieces of a virus," at best. Yet, let's be clear, if infected with a whole, live virus, rather than build immunity, you'd be depleting your cache of sick days more quickly than you might prefer.

Each season, health officials release new strains of the vaccine in an effort to stay one step ahead of whatever strain of flu virus decides to make an appearance, essentially "gambling," in Radspinner's eyes.

"Add to that the crazy pandemics like bird flu and H1N1, and you really have to think, 'How do I do a better job? This is not very effective or efficient.'"

The news is worse if you're over 65. Older, weaker immune systems need more kick than a dead virus provides to

generate a strong response, Radspinner says. This age group is also at a greater risk for flu-related complications.

REDEE FLU is instead a live replication-deficient vaccine. In English, that means you are given a dose of a live virus, but instead of the virus replicating in your cells and sending you to the ER, it screeches to a stop after just one cycle. Your body reacts with an immune response and you're primed, as if you've been infected.

"REDEE FLU will generate a more robust response because the body recognizes it as more like a real flu infection," Radspinner says.

The most profound trait of REDEE FLU is that it has hints of being a "universal vaccine" (a buzzword in today's biopharma world). Thus, in addition to protecting against seasonal flu, it may protect against pandemic flus - at least giving a body enough defense until a specific vaccine can be developed and released.

"This would ultimately change the way people are vaccinated," Radspinner says.

Aichmophobics, take note: A parallel project of FluGen's is the refinement of an intradermal delivery technology that

uses a microneedle in place of the intimidating hypodermic needle. It's modeled after the more than hundred-year-old Mantoux technique, the leading tuberculosis screening method, but lagging technology precluded its widespread use for vaccine delivery.

Now, FluGen is testing its device's ability to deliver vaccines to protect against illnesses like dengue fever and human papillomavirus. What's good about it, other than that it doesn't induce bouts of crying, is that the skin has superior immunogenicity to an injection into the muscle or subcutaneous space. For now, says Radspinner, FluGen is the only company that can inject a full dose in this way.

"Other companies have tried," he says. He cites competitor Sanofi Pasteur, whose FluZone ID (available this flu season) can inject about 20% of a full dose, which may actually be enough if given intradermally.

So, how can FluGen's device deliver full doses? It's all in the design. It uses an array of hollow microneedles made of medical-grade plastic, compared to others composed of fewer, metal needles. FluGen is able to fit an array of six needles, each with three ports, into each microneedle. When injected, a vaccine takes the path of least resistance, flowing easily in 18 directions.

Radspinner brings up the example of HPV, a virus that health officials recommend adolescent girls be vaccinated against. It's given in three doses over six months, but after the first and second doses, adoption rates plummet. This may put girls at risk, since all three doses are recommended for maximum effectiveness. FluGen is looking at delivering the full regimen in two pain-free doses.

FluGen expects to be testing the intradermal device on people in the clinic in 2014, and plans to introduce its research on REDEE FLU at the World Health Organization influenza meeting in Hong Kong this January. The two may eventually pair up.

"We'll test it with REDEE FLU. The device will help improve the efficacy of flu vaccines, but we don't have to have them come together," Radspinner says.

But back to this winter's flu shot. Get it, or rely on luck and DayQuil? While you probably won't be among those hospitalized for the flu (last season, 56 people in Dane County were so unlucky), decide quickly. The county's first confirmed case of seasonal flu came early last year, in October, underscoring Radspinner's parting advice: When it

comes to getting the flu shot, even the one making the rounds for now, "the earlier, the better."

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