

US: 160M doses of swine flu vaccine due in Oct.

July 23 2009, By LAURAN NEERGAARD, AP Medical Writer

(AP) -- The U.S. expects to have 160 million doses of swine flu vaccine available sometime in October, even though manufacturers worldwide are having serious trouble brewing the shots, federal health officials said Thursday.

At the expected two doses a person, that much would cover only a fraction of the populations that this new <u>influenza strain</u> is sickening the most - school-age children, teenagers and young adults. More vaccine would trickle out over the following months.

But a surprise bright spot: The U.S. has the world's only nasal-spray flu vaccine, and FluMist's maker announced Thursday that it's producing plenty - so many millions of doses a month that it can't keep up with putting them into the special sprayer required to use it. So Maryland-based MedImmune Inc. is working with the government to see if it can race out a different method for fall, simply dripping its swine flu vaccine into people's noses.

"A dropper instead of a sprayer works as well," said MedImmune vice president Dr. Ben Machielse.

The <u>Food and Drug Administration</u> called together five of the world's leading flu vaccine makers Thursday - all the U.S. suppliers, four of whom produce for much of the rest of the world, too - for the first indepth progress report on the quest for vaccinations.



Companies making swine flu shots are struggling. The chief ingredient for influenza vaccine is grown in chicken eggs, and companies are getting far fewer doses per egg - 30 percent of the normal yield for regular winter flu vaccine, said Jerry Weir, an FDA official who oversees that production.

The <u>World Health Organization</u> said last week that it would try to get manufacturers some better-growing strains to help.

The U.S. estimates for its October supply took that problem into account, said Robin Robinson of the Department of Health and Human Services, which is buying the nation's swine flu supply and will decide who should receive it. But that estimate also assumes that two low-dose shots, about a month apart, will offer enough protection.

Government and company-run studies of thousands of volunteers will begin in a few weeks to see if a low-dose shot really works, or if people will need higher-dose shots, further cutting the early available supply.

Not included in that calculation are MedImmune's potential extras. It used a different "seed virus" to grow vaccine than other manufacturers, because it's a different type of vaccine: Flu shots are made of killed influenza virus, while FluMist is a live but weakened strain. It comes in a set dose, and MedImmune said it will have 14 million swine flu nasal sprays available by October, and 40 million by year's end. But overall it's producing roughly 35 million doses a month, Malchielse said, if only it could turn that bulk product into a form easily administered to people.

The good news: Despite a brisk flu season in the Southern Hemisphere, the new swine flu isn't yet mutating to become more dangerous, said Dr. Nancy Cox of the Centers for Disease Control and Prevention.

"It's actually quite surprising," Cox said, that the virus is showing so little



genetic variation given its rapid spread - sickening more than a million people in the U.S. alone since April and circling the globe in a matter of weeks.

People under 25 get sick most often, although most of the 262 deaths recorded in the U.S. so far have been in 25- to 49-year-olds. People older than 65 are far less likely to get swine flu, perhaps because of years of exposure to viruses in the same H1N1 influenza family. But when they do, CDC said their risk of death is somewhat higher than the risk for other adults.

Just how risky the virus proves to be is one key to how much pressure the government feels under to start vaccinations.

The FDA said Thursday that scientifically, the new swine flu vaccine is no different than what happens every year - the flu vaccine is brewed with a different strain. Usually, makers aren't required to do special studies for merely changing the recipe. The FDA does plan to require studies of the swine flu vaccine as an extra precaution and for dose information, but may not wait on all the results before formally licensing each company's version, lifting some red tape to speed availability.

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Citation: US: 160M doses of swine flu vaccine due in Oct. (2009, July 23) retrieved 20 March 2024 from https://medicalxpress.com/news/2009-07-160m-doses-swine-flu-vaccine.html

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