

High-Dose Flu Shot Shows Promise in Elderly

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Oct 08, 2013

SAN FRANCISCO — An increased dose of influenza vaccine stimulates a greater immune response than the standard dose in long-term care residents older than 65 years, according to a new study.

"The superiority of high-dose influenza vaccine was demonstrated for all influenza strains except A/H1N1 in 2012-2013," said Richard Zimmerman, MD, from the University of Pittsburgh in Pennsylvania.

Dr. Zimmerman presented the findings here at IDWeek 2013.

Standard influenza vaccines don't produce as good an immune response in the frail elderly as they do in younger, healthier populations, Andrew Pavia, MD, chief of pediatric infectious diseases at the University of Utah in Salt Lake City, who was not involved in the study, told *Medscape Medical News*.

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"When flu moves through a nursing home, there are often dozens of deaths," he said.

Fluzone, a high-dose influenza vaccine made by Sanofi Pasteur, was approved by the US Food and Drug Administration in 2009 for use in adults older than 65 years. The vaccine delivers 4 times the standard dose of antigen, and approval was based primarily on a study in healthy community-dwelling adults with a mean age of 73.

"It may not be possible to extrapolate these results to frail long-term care residents," said Dr. Zimmerman.

To find out how the high-dose vaccine would work in this population, Dr. Zimmerman and his team vaccinated 205 residents in various long-term care facilities, including skilled nursing, assisted living, dementia care, and independent living facilities during the 2011-12 and 2012-13 flu seasons.

The investigators randomly assigned these residents to receive either regular-dose or high-dose vaccine. Of the 169 participants who completed the study, 87 received the regular dose and 82 received the high dose.

These residents were all older than 65 years and required assistance with daily activities such as shopping and dressing. The mean age of those who completed the study was 87.

The patients reported no serious adverse reactions, said Dr. Zimmerman.

The investigators measured the blood concentration of hemagglutination inhibition antibodies to 3 strains of influenza virus before the vaccinations and 1 month later.

They found no significant differences between the 2 groups at baseline. A month later, the concentration of antibodies increased in all the subjects, but they generally increased more in those who received the high-dose vaccination.

Table. Flu Season Geometric Mean Antibody Titers Before and After Vaccination

| Influenza Vaccine Strain | Standard Dose | High Dose | P Value |
|---------------------------|---------------|-----------|---------|
| Before Vaccination | | | |
| A/California/07/2009 | 33.6 | 23.1 | 0.130 |
| A/Victoria/63/2011 | 6.1 | 7.4 | 0.07 |
| B/Wisconsin/1/2010 | 9.4 | 7.9 | 0.20 |
| After Vaccination | | | |
| A/California/07/2009 | 51.6 | 45.6 | 0.590 |
| A/Victoria/63/2011 | 13.4 | 25.0 | 0.002 |
| B/Wisconsin/1/2010 | 18.7 | 25.6 | 0.045 |

Antibodies did not increase in response to the A/California/07/2009 strain vaccine in the 2012-13 season, possibly because 30% of the subjects participated in both seasons, and the A/H1N1 strains were identical those 2 seasons, explained Dr. Zimmerman.

He pointed out that the study had several limitations. The sample size was small, it was conducted over 2 years, only the patients were blinded to which vaccine they were getting, and it is not known how the antibody count correlates to actual resistance to influenza.

Dr. Pavia said that this last question is crucial. "We know it produces high antibody titers, but does it produce less disease?" he asked.

In August, [Sanofi Pasteur announced](#) that a large community-based clinical trial had shown that the high-dose vaccine was 24.2% more effective in preventing influenza in adults 65 years and older than the standard vaccine.

Dr. Pavia said he is looking forward to the data from that trial, which Sanofi Pasteur has not yet released.

Nailing down the relative benefits of a higher-dose vaccine is important, he noted. Because vaccines can sometimes be in short supply, public health officials are always trying to find the smallest dose that can produce immunity.

"This is important when you're talking about developing a vaccine in a hurry or in a developing country," said Dr. Pavia.

This study was funded by Sanofi Pasteur, and Dr. Zimmerman reports receiving grants from the company. Dr. Pavia has disclosed no relevant financial relationships.

IDWeek 2013. Abstract 576B. Presented October 3, 2013.

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Cite this article: High-Dose Flu Shot Shows Promise in Elderly. *Medscape*. Oct 08, 2013.