

High-dose equal to standard flu vaccine for risk of death or heart, lung hospitalization

November 17 2020



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People with heart disease can receive either the high-dose or standard-dose flu vaccines for protection from heart or lung-related deaths or hospitalizations, according to late breaking research presented today at the American Heart Association's Scientific Sessions 2020.

People with [heart](#) disease are at increased risk for complications from [influenza](#), including heart attacks, hospitalizations for heart failure and death. Researchers for the Influenza Vaccine to Effectively Stop Cardio Thoracic Events and Decompensated Heart Failure (INVESTED) study, funded by the National Heart, Lung, and Blood Institute of the National Institutes of Health, set out to evaluate whether a higher dose [flu vaccine](#) offered more protection against those complications, compared to a standard-dose flu vaccine. The [high-dose](#) vaccine is currently approved in the United States for people ages 65 or older and has been shown to reduce the incidence of influenza infection in these patients.

"Since people with [chronic conditions](#) have been shown to exhibit reduced immune responses to the flu vaccine, we conducted a trial to determine if a higher dosage would overcome the lower response and better protect high-risk individuals," said Orly Vardeny, Pharm.D., M.S., lead researcher of the study and an associate professor at the University of Minnesota Medical School and in the College of Pharmacy in Minneapolis. "We found that the higher dose influenza vaccine was not more effective than the standard dose in lowering the risk of death or hospitalizations from heart or lung-related illnesses."

INVESTED is a randomized, double-blind, active-controlled trial that enrolled more than 5,000 (5,260) participants across 157 clinical sites in the U.S. and Canada. Eligible participants had a recent [heart attack](#) or were hospitalized for [heart failure](#) in the previous two years. They also had at least one additional risk factor such as kidney disease, diabetes, stroke, peripheral artery disease, a weak heart muscle or current use of tobacco.

Researchers randomized participants equally to receive either a high-dose trivalent [influenza vaccine](#), which contained higher doses but only three strains of the inactive flu virus, or a standard-dose, quadrivalent vaccine including four strains of influenza. Participants could remain in

the study for up to three years, between the 2016 and 2019 flu seasons, and received the same type of vaccine each year they were in the study. There was no difference in the rates of mortality or hospitalizations for cardiac or pulmonary causes between vaccine formulations (44.5 per 100 patient years for those who received the high-dose vaccine, compared with 41.9 per 100 patient years for those who received standard-dose).

"There are several possible explanations for our findings. First, we enrolled people at high risk for heart and lung-related hospitalizations, and there were many of these types of hospitalizations during the trial. However, only a small number of those hospitalizations were identified as caused by influenza," said Vardeny who is also a core investigator with the Center for Chronic Disease Outcomes Research at the Minneapolis VA Health System. "It is possible that since all participants received the flu vaccine, both formulations similarly reduced the risk for heart and lung hospitalizations. Another possibility is that since participants were already at a very high risk for hospitalization due to their pre-existing heart conditions, and most of the hospitalizations were not attributable to influenza, the incremental benefit of one vaccine over the other would not have overcome the high underlying risk in this population."

She also noted it is possible that the extra influenza strain present in the standard-dose vaccine might have offset the benefit of the higher dose.

Researchers did not collect information on how many participants became sick with the flu, so they do not know if the higher dose of the vaccine reduced overall flu infections more than the standard dose in study participants.

Vardeny said future research should examine whether other types of the flu vaccine may be more protective for patients with high-risk conditions or whether the high-dose vaccine is more effective in low-risk cardiac

patients.

"Most importantly, these data don't detract from the extremely strong recommendation that all patients with [heart disease](#) get vaccinated for influenza. This is especially the case this year, when influenza will be co-circulating with SARS-CoV-2, the virus that causes COVID-19," Vardeny said. "Our study showed that [vaccine](#) dose may not be as important as getting vaccinated."

More information: www.abstractsonline.com/pp8/#!/9144/session/1458

Provided by American Heart Association

Citation: High-dose equal to standard flu vaccine for risk of death or heart, lung hospitalization (2020, November 17) retrieved 2 May 2024 from <https://medicalxpress.com/news/2020-11-high-dose-equal-standard-flu-vaccine.html>

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