

INFORMATION PAPER

DHA-IHB
18 October 2016

SUBJECT: Influenza Vaccines for Adults 65 Years and Older

1. Purpose. To provide guidance to health care providers on discussing the annual influenza vaccination with persons aged 65 years and older.
 - a) Annual influenza vaccination for adults 65 years and over is especially important because they are at high risk for complications from influenza. People 65 years and older may receive any injectable vaccine approved for this age group. The Centers for Disease Control and Prevention (CDC) and the Advisory Committee on Immunization Practices (ACIP) have not expressed a preference for any flu vaccine indicated for people 65 years and older.
 - b) The Department of Defense (DoD) is dedicated to providing influenza immunization to beneficiaries and endorses the importance of annual influenza vaccination as a primary intervention to protect our population.
 - c) Multiple vaccines are approved for people 65 years and older for the 2016-2017 season:
 - Inactivated Influenza Vaccine, quadrivalent (IIV4)
 - Fluarix Quadrivalent (GlaxoSmithKline)
 - Flulaval Quadrivalent (ID Biomedical Corp. of Quebec (distributed by GlaxoSmithKline))
 - Fluzone Quadrivalent (Sanofi Pasteur)
 - Flucelvax Quadrivalent (Seqirus)
 - Inactivated Influenza Vaccine, trivalent (IIV3)
 - Afluria (Seqirus)
 - Fluvirin (Seqirus)
 - Adjuvanted Inactivated Influenza Vaccine, trivalent (aIIV3)
 - Fluad (Seqirus)
 - Inactivated Influenza Vaccine, trivalent (IIV3, High Dose)
 - Fluzone High-Dose (Sanofi Pasteur)
 - Recombinant Influenza Vaccine, trivalent (RIV3)
 - Flublok (Protein Sciences)
 - There are two vaccines designed specifically for people 65 years and older, Fluzone High Dose (IIV3) and Fluad (aIIV3).
 - Fluzone High Dose (HD) (IIV3, Sanofi Pasteur)
 - Received licensure from the Food and Drug Administration in 2009
 - Contains four times more antigen (the part of the vaccine that prompts the body to make antibody) than regular influenza vaccines.

- A higher dose of antigen in the vaccine is supposed to give older people a better immune response, and therefore, better protection against flu.
 - Data from clinical trials indicate higher antibody levels are produced, but whether or not these higher levels lead to greater protection is the topic of ongoing research
 - Results from a clinical trial of more than 30,000 participants showed that adults 65 years and older who received the high dose vaccine had 24% fewer influenza infections as compared to those who received the standard dose flu vaccine. The confidence interval for this result was 9.7% to 36.5%.
 - Based on CDC/ACIP recommendations, Fluzone High Dose is an acceptable alternative to other vaccines licensed for people 65 years and older. There is no preferential recommendation made for any flu vaccine formulation for this age group.
- Fluad (allIV3, Seqirus)
 - Received licensure from the Food and Drug Administration in 2015; this vaccine is new for this season
 - Standard-dose, three-component (trivalent) inactivated flu vaccine that contains an adjuvant, MF59
 - An adjuvant is an ingredient added to a vaccine that helps create a stronger immune response to vaccination.
 - MF59 is an oil-in-water emulsion of squalene oil. Squalene, a naturally occurring substance found in humans, animals and plants, is highly purified for the vaccine manufacturing process.
 - Studies have found that antibody levels were comparable to levels induced by unadjuvanted trivalent seasonal flu vaccines (e.g., Agriflu).
 - An observational study conducted in Canada found that FLUAD was significantly more effective in preventing laboratory-confirmed influenza compared with an unadjuvanted standard-dose inactivated influenza vaccine.
 - There are no studies comparing FLUAD and Fluzone HD
 - Based on CDC and ACIP recommendations, FLUAD is now an acceptable alternative to other vaccines licensed for people 65 years and older. There is no preferential recommendation made for any flu vaccine formulation for this age group.
- The high dose and adjuvanted flu vaccines may result in more mild side effects than those that can occur with standard-dose seasonal shots. Mild side effects can include pain, redness or swelling at the injection site, headache, muscle ache and malaise.

2. Preventive Medicine representatives of each Service decide annually which influenza vaccines will be included in bulk vaccine procurement under the DoD Annual Influenza Program; the annual selection is based on CDC/ACIP recommendations.

- For the 2016-2017 season, Fluzone Pediatric (IIV4, 6 through 35 months), FluLaval (IIV4, ≥3 yrs), Fluarix (IIV4, ≥3 yrs), Afluria (IIV3, ≥9 yrs) were selected for bulk contract procurement.
- The bulk procurement of influenza vaccine is selected to meet the needs of Medical Treatment Facilities (MTFs) in protecting military and beneficiary populations with approved and recommended influenza vaccine.
- DoD MTFs can order vaccines not included in bulk procurement through the Defense Logistics Agency Troop Support Medical Direct Vendor Delivery program, via Military Standard Requisitioning and Issue Procedures (DHA-IPM 16-002).
- TRICARE pharmacy benefits cover all CDC/ACIP recommended influenza vaccines at participating network pharmacies.
 - Only vaccines given by a pharmacist are covered by the pharmacy benefit for free; if a vaccine is administered by a provider at an onsite clinic, the beneficiary may have to pay the entire cost.

3. Key Points

- Annual influenza vaccination is important for people aged 65 years and older.
- There is no CDC/ACIP preferential recommendation made for any flu vaccine formulation for people aged 65 years and older.
- The CDC/ACIP will continue to review available evidence regarding possible increased protection by vaccines designed specifically for this population (Fluzone HD (IIV3) and Fluad (aIIV3)); evidence is not yet sufficient to recommend any one vaccine over others for this population.
- The DoD Influenza Program bulk procurement provides three recommended vaccines for people aged 65 years and older: FluLaval (IIV4, ≥3 yrs), Fluarix (IIV4, ≥3 yrs), Afluria (IIV3, ≥9 yrs).

Approved by: Deputy Chief, IHB