This influenza season, multiple formulations of influenza vaccine are available for persons aged 65 years and older from a variety of manufacturers. The Centers for Disease Control and Prevention (CDC) does not state a preference for adjuvanted*, high- or standard-dose influenza vaccine for persons 65 years and older\(^1\). If multiple vaccine types are available, the Vaccine Advisory Committee recommends that healthcare providers consider the following information when discussing vaccine choices with their patients.

*An adjuvant is a substance that enhances the body’s immune response to a vaccine

Immunogenicity and clinical efficacy/effectiveness

- **Fluzone High-Dose (IIV3)** – contains four times the amount of antigen of the standard-dose flu vaccine and has been shown to produce a higher antibody response than standard-dose vaccine in older adults.\(^2\)
  - One randomized controlled trial comparing the efficacy of high- vs. standard-dose influenza vaccine showed the high-dose vaccine had 24\% greater efficacy against any laboratory-confirmed influenza infection compared to standard-dose flu vaccine (95\% CI: 9.7\%-36.5\%); 1.4\% of participants receiving high-dose vaccine and 1.9\% of participants receiving standard-dose vaccine developed laboratory-confirmed influenza during the 2011–2012 and 2012–2013 seasons. Based on this study, the high-dose vaccine would prevent about 5 additional cases of laboratory-confirmed influenza for every 1000 people vaccinated.\(^3\)
  - Studies suggest high-dose flu vaccine is likely more effective than standard-dose vaccine in preventing medically-attended, laboratory-confirmed influenza infection and some serious complications of influenza.\(^4,5\)

- **FLUAD™ (allIIV3)** – contains MF-59 adjuvant. Approved through accelerated-approval process in November 2015\(^6,7\), FLUAD™ is the first adjuvanted influenza vaccine marketed in the United States and is FDA licensed for use starting this season.
  - FLUAD™ has been shown to induce antibody levels similar to those induced by influenza vaccine without adjuvant.\(^7\)
  - A case-control study performed during the 2011–2012 season showed that an MF59 adjuvanted influenza vaccine was more effective at preventing lab-confirmed influenza infection in the elderly compared to a trivalent vaccine without an adjuvant.\(^8\)

- To date, there have been no randomized studies comparing Fluzone high-dose and FLUAD™.

Safety

- **Fluzone High-Dose (IIV3):** The safety profile of high-dose vaccine is similar to that of standard-dose flu vaccines. The high-dose vaccine is associated with more frequent injection site reactions, including injection site pain (36\% vs. 24\% with standard-dose) and moderate and severe fever (1.1\% vs. 0.3\%).\(^9\) The most common adverse events have been mild and
temporary, and include pain, redness and swelling at the injection site, headache, muscle aches, fever and malaise.

- **FLUAD™ (aIV3)**: Some adverse events are reported more frequently after vaccination with FLUAD™ than vaccines without adjuvants. The most common adverse events experienced during clinical studies with FLUAD™ were mild to moderate, and included pain, redness at the injection site, headache, and muscle aches.7

**Vaccine Advisory Committee Recommendation**

- Health care providers should offer high-dose or adjuvanted vaccine to patients 65 years of age or older when these formulations are available, but should not delay standard-dose vaccination if it is the only vaccine option available.

**References**


2. CDC. Licensure of a high-dose inactivated influenza vaccine for persons aged >65 years (Fluzone High-Dose) and guidance for use – United States, 2010. MMWR 2010;59(16):485-486. (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5916a2.htm)


**Other Resources**

CDC: http://www.cdc.gov/flu/protect/vaccine/qa_fluzone.htm

CDC: http://www.cdc.gov/flu/protect/vaccine/adjuvant.htm

CDC Vaccine Adjuvants: http://www.cdc.gov/vaccinesafety/Concerns/adjuvants.html

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