What CDC Does

FluVaxView
Communications Resource Center
International Work
Outbreak Investigations

Safety of Influenza Vaccines

Español

Safety of Inactivated Influenza Vaccines (IIVs)

Children +

Adults +

Persons at Higher Risk of Influenza-Related Complications +

Immunocompromised Persons and Transplant Recipients +

IIVs and Checkpoint Inhibitors +

Guillain-Barré Syndrome and IIVs +

Thimerosal +

Adjuvants +

Ocular and Respiratory Symptoms after Receipt of IIV +

Top of Page

Safety of Recombinant Influenza Vaccines (RIVs)

RIV was initially available in the U.S. during the 2013-14 season as RIV3 (Flublok, Protein Sciences, Meriden, Connecticut). RIV4 (Flublok Quadrivalent, Protein

Influenza Types

Seasonal

Pandemic

Avian

Swine

Influenza in Animals

Sciences, Meriden Connecticut; now manufactured by Sanofi Pasteur, Swiftwater, Pennsylvania) was licensed in late 2016 and was first available for the 2017-18 season. Since the 2018-19 season, all RIV in the U.S. is quadrivalent (RIV4). RIV4 contains HA which is produced via introduction of the HA genetic sequence into an insect cell line, and contains some residual insect proteins (124).

In pre-licensure studies of RIV4, the most frequently reported injection site reaction (reported in ≥10% of recipients) were tenderness (48% among those aged 18 through 49 years; 34% among those aged ≥50 years) and pain (37% and 19%, respectively). The most common solicited systemic reactions were headache (20% and 13%, respectively), fatigue (17%, and 12%, respectively), myalgia (13% among those aged 18 through 49 years) and arthralgia (10% among those aged 18 through 49 years) (124). In pre-licensure studies comparing safety of RIV4 with licensed comparator IIV4s among persons aged 18 through 49 years and ≥50 years, the frequency of injection site and systemic solicited AEs was generally similar between the two groups (282).

As a relatively new category of vaccine, fewer post-marketing safety data have accumulated for RIVs. Although RIVs do not contain egg protein, anaphylactic and other, less severe reactions have been reported to VAERS (520), illustrating that allergic reactions to influenza vaccines can occur in the absence of egg proteins. In a randomized study conducted among adults 50 years of age and older in which incidence of rash, urticaria, swelling, or other potential hypersensitivity reactions were actively solicited for 30 days following vaccination, 2.4% of RIV3 recipients and 1.6% of IIV3 recipients reported such events within the 30 day follow-up period. A total of 1.9% and 0.9% of RIV3 and IIV3 recipients, respectively, reported these events within 7 days following vaccination. Of these solicited events, rash was most frequently reported (RIV3 1.3%; IIV3 0.8%) over the 30 day follow-up period (521).

Safety of Live Attenuated Influenza Vaccine (LAIV)

Shedding, Transmission, and Phenotypic Stability of LAIV Viruses +

Children +

Adults +

Persons at Higher Risk of Influenza-Related Complications +

Other Influenza Vaccine Safety Information

Influenza Vaccine Safety in Pregnant Women and Neonates +

Immediate Hypersensitivity Reactions after Receipt of Influenza Vaccines +

Influenza Vaccination and Egg Allergy +

Top of Page

Immunogenicity, E...

References

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