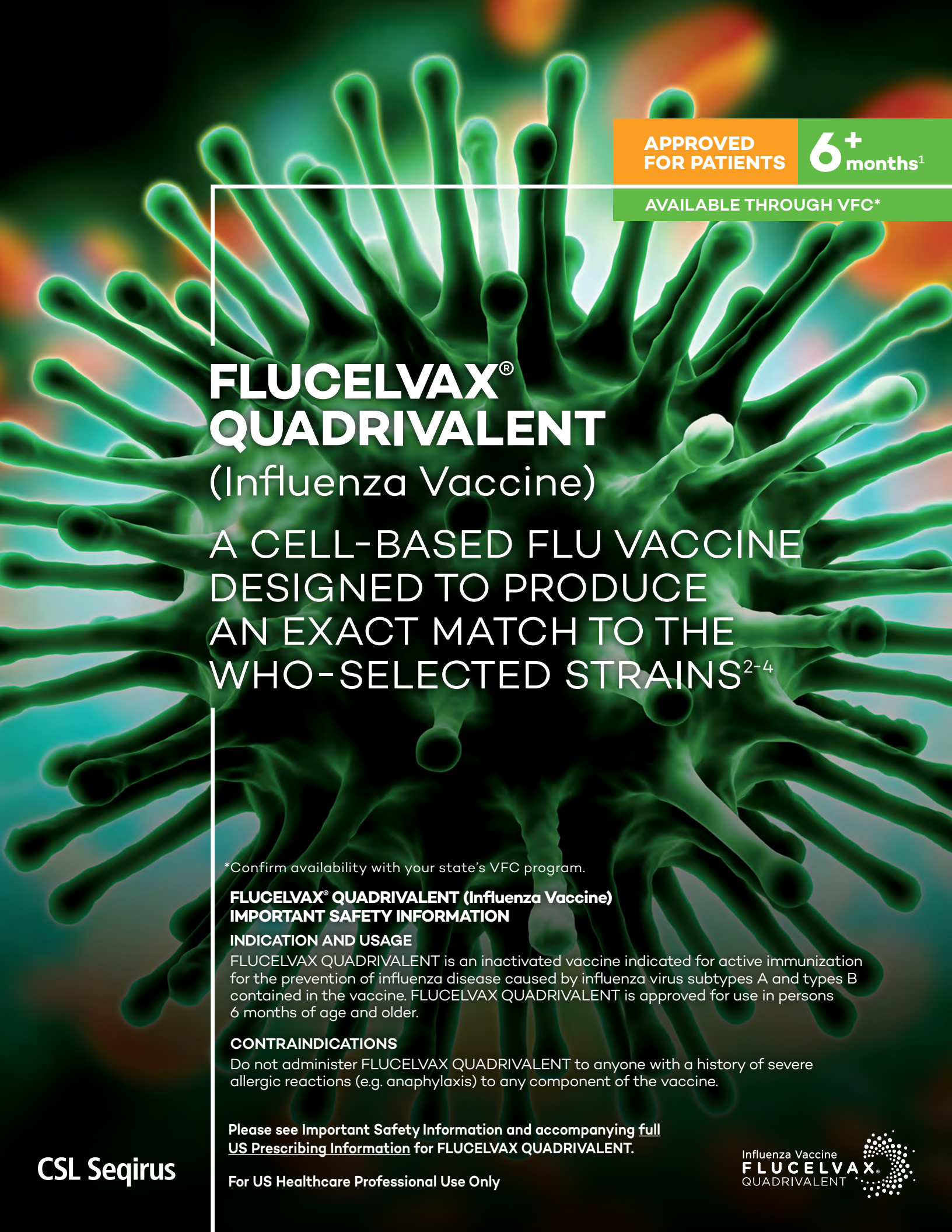


APPROVED FOR PATIENTS 6+ months[1]

AVAILABLE THROUGH VFC*

FLUCELVAX® QUADRIVALENT

(Influenza Vaccine)

A CELL-BASED FLU VACCINE DESIGNED TO PRODUCE AN EXACT MATCH TO THE WHO-SELECTED STRAINS[2-4]

*Confirm availability with your state's VFC program.

FLUCELVAX® QUADRIVALENT (Influenza Vaccine)
IMPORTANT SAFETY INFORMATION

INDICATION AND USAGE

FLUCELVAX QUADRIVALENT is an inactivated vaccine indicated for active immunization for the prevention of influenza disease caused by influenza virus subtypes A and types B contained in the vaccine. FLUCELVAX QUADRIVALENT is approved for use in persons 6 months of age and older.

CONTRAINDICATIONS

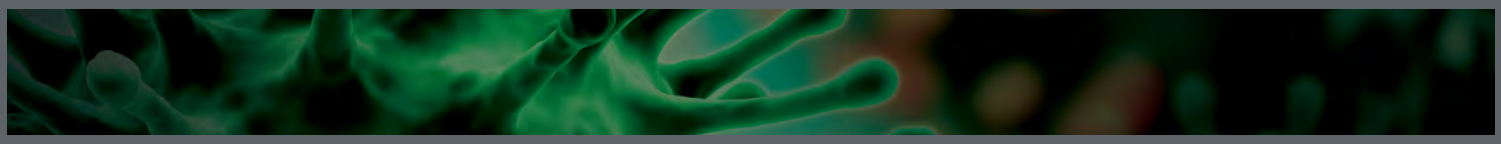
Do not administer FLUCELVAX QUADRIVALENT to anyone with a history of severe allergic reactions (e.g. anaphylaxis) to any component of the vaccine.

Please see Important Safety Information and accompanying full US Prescribing Information for FLUCELVAX QUADRIVALENT.

For US Healthcare Professional Use Only

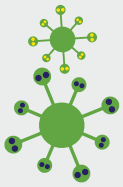
CSL Seqirus

Influenza Vaccine FLUCELVAX® QUADRIVALENT



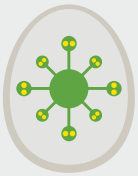
SEVERAL FACTORS MAY IMPACT INFLUENZA VACCINE EFFECTIVENESS

Two that may play an important role include strain mismatch due to **antigenic drift** or **egg adaptation** and characteristics of the vaccine recipient, such as health status and age[4-7]



ANTIGENIC DRIFT

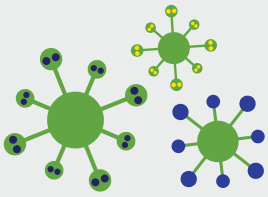
After vaccine strain selection, circulating influenza virus strains have the potential to mutate, which can impact vaccine effectiveness.[5]



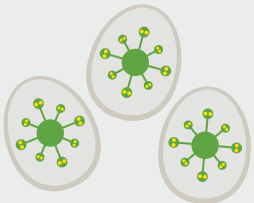
EGG ADAPTATION

A mismatch can also be introduced during egg-based influenza vaccine production. In order for human viruses to grow well in eggs, the hemagglutinin (HA) must adapt to bind to avian receptors.[4,6,7]

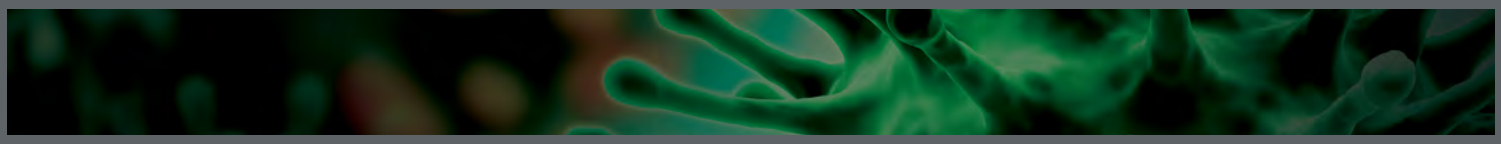
For US influenza seasons 2010-2011 through 2019-2020[6-16]



A strain mismatch occurred in **7 of the 10** US influenza seasons

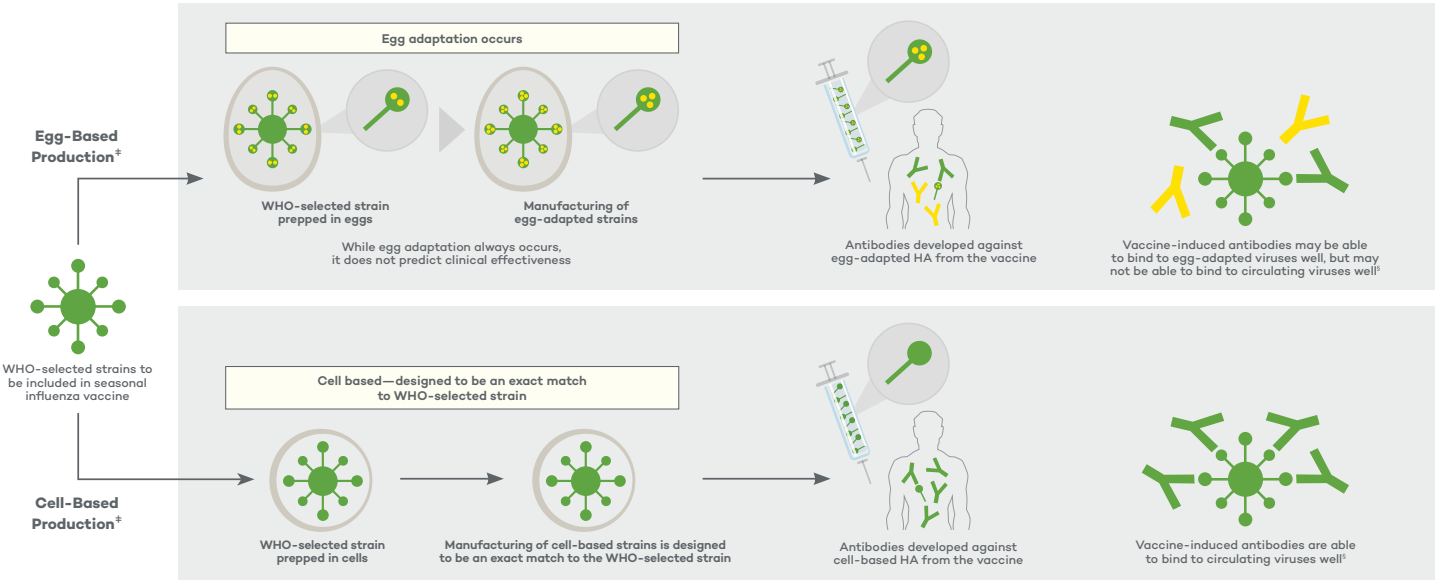


Nearly half of them were caused by egg adaptation in the vaccine strains during production



CELL-BASED INFLUENZA VACCINES AVOID EGG ADAPTATION

Some egg-adaptive mutations may cause HA to be antigenically different from the WHO-selected strains.[†2,4,17]



CELL-BASED INFLUENZA VACCINES ARE DESIGNED TO PRODUCE AN EXACT MATCH TO THE WHO-SELECTED STRAIN[†2-4]

WHO=World Health Organization

†Match to the WHO-selected strain(s) does not predict clinical effectiveness

‡These graphics provide a simplified overview of the egg-based and cell-based influenza vaccine production processes

§This depiction assumes the circulating strain matches the WHO-selected strain

FLUCELVAX® QUADRIVALENT (Influenza Vaccine) IS APPROVED FOR PATIENTS 6+ MONTHS[1]

- Cell-based influenza vaccines are designed to produce an exact match to the WHO-selected strains[2-4]
- Efficacy of FLUCELVAX QUADRIVALENT was demonstrated in children and adolescents 2 through 17 years[1]
- Proven noninferior to a US-licensed comparator quadrivalent influenza vaccine based on immunogenicity and seroconversion for patients 6 months through 3 years[1]
- Proven noninferior to FLUCELVAX® (Influenza Vaccine) based on immunogenicity and seroconversion for patients 4 years and older[1]
- Do not administer FLUCELVAX QUADRIVALENT to anyone with a history of severe allergic reactions (eg, anaphylaxis) to any component of the vaccine[1]
- FLUCELVAX QUADRIVALENT is free of eggs and antibiotics[1]

Presentation	Carton NDC	Syringe/Vial Label NDC
Pack of 10 x 0.5-mL pre-filled syringes (contain no preservative)	70461-322-03	70461-322-04
5-mL multi-dose vial (contains thimerosal)	70461-422-10	70461-422-11

REIMBURSED THROUGH CPT CODES:

90674—SINGLE-DOSE SYRINGE
90756—MULTI-DOSE VIAL

CPT=Current Procedural Terminology

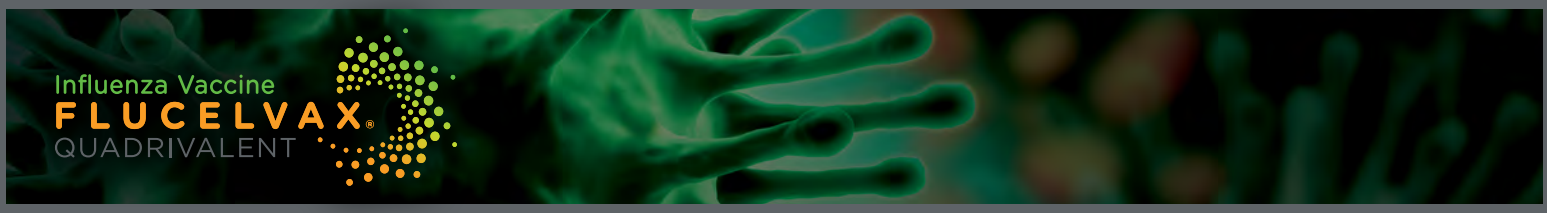
Available through Vaccines for Children (VFC) and reimbursed by Medicare Part B and most major health plans#

#This information does not constitute a guarantee or warranty of coverage benefits or reimbursement. Confirm availability with your state's VFC program.

Please see Important Safety Information and accompanying full US Prescribing Information for FLUCELVAX QUADRIVALENT.

For US Healthcare Professional Use Only

Influenza Vaccine
FLUCELVAX®
QUADRIVALENT



FLUCELVAX® QUADRIVALENT (Influenza Vaccine) IMPORTANT SAFETY INFORMATION

INDICATION AND USAGE

FLUCELVAX QUADRIVALENT is an inactivated vaccine indicated for active immunization for the prevention of influenza disease caused by influenza virus subtypes A and types B contained in the vaccine. FLUCELVAX QUADRIVALENT is approved for use in persons 6 months of age and older.

CONTRAINDICATIONS

Do not administer FLUCELVAX QUADRIVALENT to anyone with a history of severe allergic reactions (e.g. anaphylaxis) to any component of the vaccine.

WARNINGS AND PRECAUTIONS

If Guillain-Barré syndrome has occurred within 6 weeks of receipt of a prior influenza vaccine, the decision to give FLUCELVAX QUADRIVALENT should be based on careful consideration of the potential benefits and risks.

Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.

Syncope (fainting) can occur in association with administration of injectable vaccines, including FLUCELVAX QUADRIVALENT. Syncope can be accompanied by transient neurological signs such as visual disturbance, paresthesia, and tonic-clonic limb movements. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope by maintaining a supine or Trendelenburg position.

After vaccination with FLUCELVAX QUADRIVALENT, immunocompromised individuals, including those receiving immunosuppressive therapy, may have a reduced immune response.

Vaccination with FLUCELVAX QUADRIVALENT may not protect all vaccine recipients against influenza disease.

ADVERSE REACTIONS

In children 6 months through 3 years of age who received FLUCELVAX QUADRIVALENT, the most commonly reported injection-site adverse reactions were tenderness (27.9%), erythema (25.8%), induration (17.3%) and ecchymosis (10.7%). The most common systemic adverse reactions were irritability (27.9%), sleepiness (26.9%), diarrhea (17.9%) and change of eating habits (17.4%).

In children 2 through 8 years of age who received FLUCELVAX QUADRIVALENT, the most commonly reported injection-site adverse reactions were tenderness (28.7%), pain (27.9%) and erythema (21.3%), induration (14.9%) and ecchymosis (10.0%). The most common systemic adverse reactions were sleepiness (14.9%), headache (13.8%), fatigue (13.8%), irritability (13.8%) and loss of appetite (10.6%).

In children and adolescents 9 through 17 years of age who received FLUCELVAX QUADRIVALENT, the most commonly reported injection-site adverse reactions were injection site pain (21.7%), erythema (17.2%) and induration (10.5%). The most common systemic adverse reactions were headache (18.1%) and fatigue (17.0%).

In adults 18 through 64 years of age who received FLUCELVAX QUADRIVALENT, the most commonly reported injection-site adverse reactions were pain (45.4%), erythema (13.4%) and induration (11.6%). The most common systemic adverse reactions were headache (18.7%), fatigue (17.8%) and myalgia (15.4%).

In adults ≥65 years of age who received FLUCELVAX QUADRIVALENT, the most commonly reported injection-site adverse reactions were pain (21.6%) and erythema (11.9%).

To report SUSPECTED ADVERSE REACTIONS, contact Seqirus at 1-855-358-8966 or VAERS at 1-800-822-7967 or www.vaers.hhs.gov.

Before administration, please see the full US Prescribing Information for FLUCELVAX QUADRIVALENT.

FLUCELVAX ® QUADRIVALENT is a registered trademark of Seqirus UK Limited or its affiliates.

References: 1. FLUCELVAX QUADRIVALENT. Package insert. Seqirus Inc; 2022. **2.** Centers for Disease Control and Prevention. Cell-based flu vaccines. Accessed August 19, 2022. https://www.cdc.gov/flu/prevent/cell-based.htm **3.** Mabrouk T, Ellis RW. Influenza vaccine technologies and the use of the cell-culture process (cell-culture influenza vaccine). *Dev Biol.* 2002;110:125-134. **4.** Rajaram S, Boikos C, Daniele K, Gelone DK, Gandhi A. Influenza vaccines: the potential benefits of cell-culture isolation and manufacturing. *Ther Adv Vaccines Immunother.* 2020;8:2515135520908121. doi:10.1177/2515135520908121 **5.** Paules CI, Sullivan SG, Subbarao K, Fauci AS. Chasing seasonal influenza - the need for a universal influenza vaccine. *N Engl J Med.* 2018;378(1):7-9. **6.** Skowronski DM, Janjua NZ, De Serres G, et al. Low 2012-13 influenza vaccine effectiveness associated with mutation in the egg-adapted H3N2 vaccine strain not antigenic drift in circulating viruses. *PLoS One.* 2014;9(3):e92153. doi:10.1371/journal.pone.0092153 **7.** Zost SJ, Parkhouse K, Gumina ME, et al. Contemporary H3N2 influenza viruses have a glycosylation site that alters binding of antibodies elicited by egg-adapted vaccine strains. *Proc Natl Acad Sci USA.* 2017;114(47):12578-12583. doi:10.1073/pnas.1712377114 **8.** Centers for Disease Control and Prevention. Update: Influenza activity—United States, 2010-11 season, and composition of the 2011-12 influenza vaccine. *MMWR Morb Mortal Wkly Rep.* 2011;60(21):705-712. **9.** Ohmit SE, Thompson MG, Petrie JG, et al. Influenza vaccine effectiveness in the 2011-2012 season: protection against each circulating virus and the effect of prior vaccination on estimates. *Clin Infect Dis.* 2014;58(3):319-327. doi:10.1093/cid/cit736 **10.** McLean HQ, Thompson MG, Sundaram ME, et al. Influenza vaccine effectiveness in the United States during 2012-2013: variable protection by age and virus type. *J Infect Dis.* 2015;211(10):1529-1540. doi:10.1093/infdis/jiu647 **11.** Gaglani M, Pruszynski J, Murthy K, et al. Influenza vaccine effectiveness against 2009 pandemic influenza A(H1N1) virus differed by vaccine type during 2013-2014 in the United States. *J Infect Dis.* 2016;213(10):1546-1556. doi:10.1093/infdis/jiv577 **12.** Zimmerman RK, Nowalk MP, Chung J, et al. 2014-2015 influenza vaccine effectiveness in the United States by vaccine type. *Clin Infect Dis.* 2016;63(12):1564-1573. doi:10.1093/cid/ciw635 **13.** Jackson ML, Chung JR, Jackson LA, et al. Influenza vaccine effectiveness in the United States during the 2015-2016 season. *N Engl J Med.* 2017;377(6):534-543. doi:10.1056/NEJMoa1700153 **14.** Flannery B, Chung JR, Belongia EA, et al. Interim estimates of 2017-18 seasonal influenza vaccine effectiveness - United States, February 2018. *MMWR Morb Mortal Wkly Rep.* 2018;67(6):180-185. doi:10.15585/mmwr.mm6706a2 **15.** Flannery B, Kondor RJG, Chung JR, et al. Spread of antigenically drifted influenza A(H3N2) viruses and vaccine effectiveness in the United States during the 2018-2019 season. *J Infect Dis.* 2020;221(1):8-15. doi:10.1093/infdis/jiz543 **16.** Tenforde MW, Garten Kondor RJ, Chung JR, et al. Effect of antigenic drift on influenza vaccine effectiveness in the United States-2019-2020. *Clin Infect Dis.* 2021;73(11):e4244-e4250. doi: 10.1093/cid/ciaa1884. **17.** Subbarao K, Barr I. A tale of two mutations: beginning to understand the problems with egg-based influenza vaccines? *Cell Host Microbe.* 2019;25(6):773-775. doi:10.1016/j.chom.2019.05.012

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