

Information about the Screening Checklist for Contraindications to Inactivated Injectable Influenza Vaccination (IIV or RIV)

1. Did you receive the flu vaccine last year?

This question helps us keep our records up to date and assists us in determining the number of vaccines a child may need during the current flu season.

If the patient indicates the flu vaccine was administered at another facility please verify it is documented in the chart.

2. Has the person to be vaccinated ever had a serious reaction to influenza vaccine in the past?

Patients reporting a serious reaction to a previous dose of inactivated influenza vaccine should be asked to describe their symptoms. Immediate – presumably allergic – reactions are usually a contraindication to further vaccination against influenza.

Fever, malaise, myalgia, and other systemic symptoms most often affect people who are first-time vaccines. These mild-to-moderate local reactions are not a contraindication to future vaccination. These people can receive injectable vaccine without further evaluation.

3. Do you have an allergy to a component of the vaccine (including eggs)?

All vaccines, including influenza vaccines, contain various components that might cause allergic reactions, including anaphylaxis. Not all such reactions are related to residual egg protein; however, the possibility of a reaction to influenza vaccines in egg-allergic people might be of concern to both these people and vaccine providers.

An egg-free recombinant influenza vaccine (RIV4, Flublok; Sanofi Pasteur) is available for people age 18 years and older and an egg-free cell culture-based IIV (cclIV4, Flucelvax; Seqirus) is approved for people age 4 years and older. ACIP does not state a preference for the use of RIV4 or cclIV4 for people with egg allergy although some providers may choose to administer RIV4 or cclIV4 to their patients with a history of severe egg allergy.

Reviews of studies of egg-culture based IIV and LAIV indicate that severe allergic reactions to egg-based influenza vaccines in people with egg allergy are unlikely. ACIP recommends that people with a history of egg allergy who have experienced only hives after exposure to egg may receive any recommended influenza vaccine (IIV, RIV4, LAIV4) appropriate for their age and health status.

In people with a history of severe egg allergy who report symptoms other than hives (e.g. angioedema, respiratory distress, recurrent vomiting) or who required emergent medical intervention (e.g., epinephrine) may also receive any recommended influenza vaccine appropriate for their age and health status. If a vaccine other than cclIV4 (Flucelvax) or RIV4 (Flublok) is used, it should be administered in a medical setting (e.g., a health department or physician office) and supervised by a healthcare provider who is able to recognize and manage severe allergic conditions. Providers should consider observing all patients for 15 minutes after vaccination to decrease the risk for injury should they experience syncope.

Inactivated influenza vaccines provided in multidose vials contain thimerosal as a preservative. Most people who had sensitivity to thimerosal when it was used in contact lens solution do not have reactions to thimerosal when it is used in vaccines. Check the package insert at www.immunize.org/fda for a list of the vaccine components (i.e., excipients and culture media) used in the production of the vaccine, or go to www.fda.gov/vaccines-blood-biologics/vaccines/vaccineslicensed-use-united-states.

For the 2020–2021 influenza season, no vaccine or packaging contains latex.

4. Has the person to be vaccinated ever had Guillain-Barré syndrome?

People who are not at high risk for severe influenza complications and who are known to have developed Guillain-Barré syndrome (GBS) within 6 weeks after receiving a previous influenza vaccination should not be vaccinated. As an alternative, clinicians might consider using influenza antiviral chemoprophylaxis for these people. Although data are limited, the established benefits of influenza vaccination for the majority of people who have a history of GBS, and who are at high risk for severe complications from influenza, justify yearly vaccination.

Influenza (Flu) Vaccine (Inactivated or Recombinant): *What you need to know*

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Influenza vaccine can prevent **influenza (flu)**.

Flu is a contagious disease that spreads around the United States every year, usually between October and May. Anyone can get the flu, but it is more dangerous for some people. Infants and young children, people 65 years of age and older, pregnant women, and people with certain health conditions or a weakened immune system are at greatest risk of flu complications.

Pneumonia, bronchitis, sinus infections and ear infections are examples of flu-related complications. If you have a medical condition, such as heart disease, cancer or diabetes, flu can make it worse.

Flu can cause fever and chills, sore throat, muscle aches, fatigue, cough, headache, and runny or stuffy nose. Some people may have vomiting and diarrhea, though this is more common in children than adults.

Each year **thousands of people in the United States die from flu**, and many more are hospitalized. Flu vaccine prevents millions of illnesses and flu-related visits to the doctor each year.

2 Influenza vaccine

CDC recommends everyone 6 months of age and older get vaccinated every flu season. **Children 6 months through 8 years of age** may need 2 doses during a single flu season. **Everyone else** needs only 1 dose each flu season.

It takes about 2 weeks for protection to develop after vaccination.

There are many flu viruses, and they are always changing. Each year a new flu vaccine is made to protect against three or four viruses that are likely to cause disease in the upcoming flu season. Even when the vaccine doesn't exactly match these viruses, it may still provide some protection.

Influenza vaccine **does not cause flu**.

Influenza vaccine may be given at the same time as other vaccines.

3 Talk with your health care provider

Tell your vaccine provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of influenza vaccine**, or has any **severe, life-threatening allergies**.
- Has ever had **Guillain-Barré Syndrome** (also called GBS).

In some cases, your health care provider may decide to postpone influenza vaccination to a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting influenza vaccine.

Your health care provider can give you more information.



4 Risks of a vaccine reaction

- Soreness, redness, and swelling where shot is given, fever, muscle aches, and headache can happen after influenza vaccine.
- There may be a very small increased risk of Guillain-Barré Syndrome (GBS) after inactivated influenza vaccine (the flu shot).

Young children who get the flu shot along with pneumococcal vaccine (PCV13), and/or DTaP vaccine at the same time might be slightly more likely to have a seizure caused by fever. Tell your health care provider if a child who is getting flu vaccine has ever had a seizure.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

5 What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at www.vaers.hhs.gov or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff do not give medical advice.*

6 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines. Visit the VICP website at www.hrsa.gov/vaccinecompensation or call **1-800-338-2382** to learn about the program and about filing a claim. There is a time limit to file a claim for compensation.

7 How can I learn more?

- Ask your healthcare provider.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call **1-800-232-4636 (1-800-CDC-INFO)** or
 - Visit CDC's www.cdc.gov/flu

Vaccine Information Statement (Interim)
**Inactivated Influenza
Vaccine**



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DECLARACIÓN DE INFORMACIÓN SOBRE LA VACUNA

Vacuna contra la influenza (gripe) (inactivada o recombinante): *Lo que necesita saber*

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Muchas de las hojas de información sobre vacunas están disponibles en español y otros idiomas. Consulte www.immunize.org/vis

1 ¿Por qué es necesario vacunarse?

La **vacuna contra la influenza** puede prevenir la **influenza (gripe)**.

La **gripe** es una enfermedad contagiosa que se propaga por los Estados Unidos cada año, generalmente entre octubre y mayo. Cualquiera puede contraer la gripe, pero es más peligroso para algunas personas. Los bebés y niños pequeños, las personas de 65 años de edad y mayores, las mujeres embarazadas y las personas con ciertos padecimientos de salud o un sistema inmunitario debilitado tienen un mayor riesgo de sufrir complicaciones por la gripe.

La neumonía, la bronquitis, las infecciones sinusales y las infecciones del oído son ejemplos de complicaciones relacionadas con la gripe. Si tiene un padecimiento médico, como una enfermedad del corazón, cáncer o diabetes, la gripe puede empeorarlo.

La gripe puede causar fiebre y escalofríos, dolor de garganta, dolores musculares, fatiga, tos, dolor de cabeza y secreción nasal o congestión nasal. Algunas personas pueden tener vómito y diarrea, aunque esto es más frecuente en niños que en adultos.

Cada año, **miles de personas mueren por influenza en los Estados Unidos**, y muchas más son hospitalizadas. La vacuna contra la gripe previene millones de enfermedades y visitas al médico relacionadas con la gripe cada año.

2 Vacuna contra la influenza

Los Centros para el control y la prevención de enfermedades (Centers for Disease Control and Prevention, CDC) recomiendan que todas las personas de 6 meses de edad y mayores se vacunen cada temporada contra la gripe. **Niños de 6 meses a 8 años de edad** pueden necesitar 2 dosis durante una

sola temporada de gripe. **Todos los demás** necesitan solo 1 dosis cada temporada de gripe.

La protección tarda aproximadamente 2 semanas en desarrollarse después de la vacunación.

Hay muchos virus de la gripe y siempre están cambiando. Cada año se fabrica una nueva vacuna contra la gripe para proteger contra tres o cuatro virus que probablemente causen enfermedades en la próxima temporada de gripe. Incluso cuando la vacuna no coincide exactamente con estos virus, aún puede brindar cierta protección.

La vacuna contra la influenza **no causa gripe**.

La vacuna contra la influenza puede aplicarse al mismo tiempo que otras vacunas.

3 Hable con su proveedor de atención médica

Informe a su proveedor de vacunas si la persona que va a recibir la vacuna:

- Ha tenido una **reacción alérgica después de una dosis previa de la vacuna contra la influenza** o si ha tenido cualquier **alergia grave y potencialmente mortal**.
- Alguna vez ha tenido el **síndrome de Guillain-Barré** (también llamado SGB).

En algunos casos, su proveedor de atención médica podría decidir que se posponga la vacunación contra la influenza para una visita futura.

Se puede vacunar a personas con enfermedades leves, como la gripe. Personas con enfermedades moderadas o graves usualmente deben esperar hasta recuperarse antes de recibir la vacuna contra la influenza.

Su proveedor de atención médica puede proporcionarle más información.



4

Riesgos de una reacción a la vacuna

- Puede presentarse dolor, enrojecimiento e hinchazón donde se aplica la inyección, fiebre, dolores musculares y dolor de cabeza después de recibir la vacuna contra la influenza.
- Puede haber un aumento muy pequeño del riesgo de contraer el síndrome de Guillain-Barré (SGB) después de recibir la vacuna inactivada contra la influenza (la vacuna contra la gripe).

Los niños pequeños que reciben la vacuna contra la gripe junto con la vacuna antineumocócica (PCV13) y/o la vacuna DTaP al mismo tiempo pueden tener un poco más de probabilidades de tener una convulsión causada por la fiebre. Informe a su proveedor de atención médica si un niño que recibe la vacuna contra la influenza ha tenido convulsiones alguna vez.

En algunos casos, las personas se desmayan después de un procedimiento médico, incluida la vacunación. Informe a su proveedor de atención médica si se siente mareado o si tiene cambios en la visión o zumbido en los oídos.

Al igual que con cualquier medicina, hay probabilidades muy remotas de que una vacuna cause una reacción alérgica grave, otro daño grave o la muerte.

5

¿Qué debo hacer si hay un problema grave?

Podría ocurrir una reacción alérgica después de que la persona deje la clínica. Si observa signos de una reacción alérgica grave (ronchas, hinchazón de la cara y garganta, dificultad para respirar, latidos rápidos, mareo o debilidad), llame al **9-1-1** y lleve a la persona al hospital más cercano.

Llame al proveedor de atención médica si hay otros signos que le preocupan.

Las reacciones adversas se deben reportar al Sistema de informes de eventos adversos derivados de vacunas (Vaccine Adverse Event Reporting System, VAERS). Es usual que el proveedor de atención médica informe sobre ello, o también puede hacerlo usted mismo. Visite el sitio web de VAERS en www.vaers.hhs.gov o llame al **1-800-822-7967**. *El VAERS es solo para informar sobre reacciones y el personal de VAERS no proporciona consejos médicos.*

6

Programa nacional de compensación por lesiones ocasionadas por vacunas

El Programa nacional de compensación por lesiones ocasionadas por vacunas (National Vaccine Injury Compensation Program, VICP) es un programa federal que se creó para compensar a las personas que podrían haber experimentado lesiones ocasionadas por ciertas vacunas. Visite el sitio web de VICP en www.hrsa.gov/vaccinecompensation o llame al **1-800-338-2382** para obtener información acerca del programa y de cómo presentar una reclamación. Hay un plazo límite para presentar una reclamación de compensación.

7

¿Dónde puedo obtener más información?

- Consulte a su proveedor de atención médica.
- Llame a su departamento de salud local o estatal.
- Comuníquese con los Centros para el Control y la Prevención de Enfermedades (CDC):
 - Llame al **1-800-232-4636 (1-800-CDC-INFO)** o
 - Visite el sitio web www.cdc.gov/flu de los CDC

Vaccine Information Statement (Interim)
**Inactivated Influenza
Vaccine** Spanish



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