2021
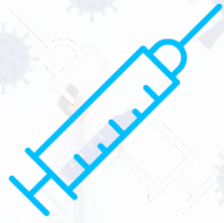
Public Health
Prevent. Promote. Protect.

Shawnee County Health Department

Shawnee County COVID-19 Vaccine
School Communications Toolkit

Shawnee County
Walk-In School Vaccine Clinics

Public Health
Prevent. Promote. Protect.
Shawnee County Health Department

Host		8:00 - 10:00am	Dates	
USD 437 – Washburn Rural High School		June 7th	June 28th	July 19th – *2nd dose only*
USD 345 – Seaman High School		June 8th	June 29th	July 20th – *2nd dose only*
USD 450 – Shawnee Heights Middle School		June 9th	June 30th	July 21st – *2nd dose only*
USD 372 & 321 – Silver Lake High School		June 10th	July 1st	July 22nd – *2nd dose only*
Private Schools – Hayden High School		June 11th	July 2nd	July 23rd – *2nd dose only*
USD 501 – Topeka Public Schools		Collaborating with KDHE		

Choose your location and get vaccinated!

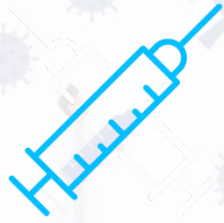**Please contact SNCOVaccine@snco.us with questions**

Eligible individuals: Anyone 12 years and older. Parental consent required for ages 12-17.
Available vaccine: Pfizer mRNA COVID-19 Vaccine
No appointment necessary. Open to all community members.
For more information on vaccine safety and information, please visit: http://www.snco.us/hd/COVID19_Vaccination.asp

Shawnee County Vaccine Clinics
USD 372 Silver Lake & USD 321 Kaw Valley

Public Health
Prevent. Promote. Protect.
Shawnee County Health Department

Host	8:00 - 10:00am	Dates	
Rossville High School	May 27th	June 17th	
	1st Dose	**2nd Dose**	
Silver Lake High School	June 10th	July 1st	July 22nd
	1st Dose	**1st & 2nd Doses**	**2nd Dose**

Choose your location and get vaccinated!

Please contact your school health professional or email SNCOVaccine@snco.us with questions

Eligible individuals: Anyone 12 years and older. Parental consent required for ages 12-17.
Available vaccine: Pfizer mRNA COVID-19 Vaccine
No appointment necessary. Open to all community members.
For more information on vaccine safety and information, please visit: http://www.snco.us/hd/COVID19_Vaccination.asp

Getting Back to Normal

Did you know?

A VACCINATED PERSON DOES NOT NEED TO QUARANTINE IF THEY MEET ALL OF THE FOLLOWING CRITERIA:

- ✓ Are fully vaccinated

- ✓ Are within 6-months following receipt of the last dose in a series

- ✓ Have remained without symptoms since COVID-19 exposure

Fully vaccinated people can safely:

- ✓ Hang out with friends!

- ✓ Go on vacation!

- ✓ Play sports!

- ✓ Dance, create music, and perform in theatre!

For more information on eligibility, ask your school health professional or visit www.shawneehealth.org and click on "Vaccine"

Public Health
Prevent. Promote. Protect.

Shawnee County Health Department

Healthy People – Healthy Environment – Healthy Shawnee County

FACT SHEET FOR RECIPIENTS AND CAREGIVERS

**EMERGENCY USE AUTHORIZATION (EUA) OF
THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS
DISEASE 2019 (COVID-19)
IN INDIVIDUALS 12 YEARS OF AGE AND OLDER**

You are being offered the Pfizer-BioNTech COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Pfizer-BioNTech COVID-19 Vaccine is a vaccine and may prevent you from getting COVID-19. There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.

Read this Fact Sheet for information about the Pfizer-BioNTech COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Pfizer-BioNTech COVID-19 Vaccine.

The Pfizer-BioNTech COVID-19 Vaccine is administered as a 2-dose series, 3 weeks apart, into the muscle.

The Pfizer-BioNTech COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.cvdvaccine.com.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?
COVID-19 disease is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS THE PFIZER-BIONTECH COVID-19 VACCINE?
The Pfizer-BioNTech COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19.

Revised: 10 May 2021

The FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19 in individuals 12 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the "**What is an Emergency Use Authorization (EUA)?**" section at the end of this Fact Sheet.

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE PFIZER-BIONTECH COVID-19 VACCINE?
Tell the vaccination provider about all of your medical conditions, including if you:
- have any allergies
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine
- have ever fainted in association with an injection

WHO SHOULD GET THE PFIZER-BIONTECH COVID-19 VACCINE?
FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine in individuals 12 years of age and older.

WHO SHOULD <u>NOT</u> GET THE PFIZER-BIONTECH COVID-19 VACCINE?
You should not get the Pfizer-BioNTech COVID-19 Vaccine if you:
- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine.

WHAT ARE THE INGREDIENTS IN THE PFIZER-BIONTECH COVID-19 VACCINE?
The Pfizer-BioNTech COVID-19 Vaccine includes the following ingredients: mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

HOW IS THE PFIZER-BIONTECH COVID-19 VACCINE GIVEN?
The Pfizer-BioNTech COVID-19 Vaccine will be given to you as an injection into the muscle.

The Pfizer-BioNTech COVID-19 Vaccine vaccination series is 2 doses given 3 weeks apart.

If you receive one dose of the Pfizer-BioNTech COVID-19 Vaccine, you should receive a second dose of this same vaccine 3 weeks later to complete the vaccination series.

Revised: 10 May 2021

HAS THE PFIZER-BIONTECH COVID-19 VACCINE BEEN USED BEFORE?
The Pfizer-BioNTech COVID-19 Vaccine is an unapproved vaccine. In clinical trials, approximately 23,000 individuals 12 years of age and older have received at least 1 dose of the Pfizer-BioNTech COVID-19 Vaccine.

WHAT ARE THE BENEFITS OF THE PFIZER-BIONTECH COVID-19 VACCINE?
In an ongoing clinical trial, the Pfizer-BioNTech COVID-19 Vaccine has been shown to prevent COVID-19 following 2 doses given 3 weeks apart. The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE PFIZER-BIONTECH COVID-19 VACCINE?
There is a remote chance that the Pfizer-BioNTech COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Pfizer-BioNTech COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:
- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

Side effects that have been reported with the Pfizer-BioNTech COVID-19 Vaccine include:
- severe allergic reactions
- non-severe allergic reactions such as rash, itching, hives, or swelling of the face
- injection site pain
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)
- diarrhea
- vomiting
- arm pain

These may not be all the possible side effects of the Pfizer-BioNTech COVID-19 Vaccine. Serious and unexpected side effects may occur. Pfizer-BioNTech COVID-19 Vaccine is still being studied in clinical trials.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?
If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to FDA/CDC Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html. Please include "Pfizer-BioNTech COVID-19 Vaccine EUA" in the first line of box #18 of the report form.

In addition, you can report side effects to Pfizer Inc. at the contact information provided below.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

You may also be given an option to enroll in v-safe. V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safe also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: www.cdc.gov/vsafe.

WHAT IF I DECIDE NOT TO GET THE PFIZER-BIONTECH COVID-19 VACCINE?
It is your choice to receive or not receive the Pfizer-BioNTech COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES PFIZER-BIONTECH COVID-19 VACCINE?
Currently, there is no approved alternative vaccine available for prevention of COVID-19. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

CAN I RECEIVE THE PFIZER-BIONTECH COVID-19 VACCINE WITH OTHER VACCINES?
There is no information on the use of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

WHAT IF I AM PREGNANT OR BREASTFEEDING?
If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

WILL THE PFIZER-BIONTECH COVID-19 VACCINE GIVE ME COVID-19?
No. The Pfizer-BioNTech COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD
When you get your first dose, you will get a vaccination card to show you when to return for your second dose of Pfizer-BioNTech COVID-19 Vaccine. Remember to bring your card when you return.

ADDITIONAL INFORMATION
If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

Global website	Telephone number
www.cvdvaccine.com	1-877-829-2619 (1-877-VAX-CO19)

HOW CAN I LEARN MORE?
- Ask the vaccination provider.
- Visit CDC at https://www.cdc.gov/coronavirus/2019-ncov/index.html.
- Visit FDA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.
- Contact your local or state public health department.

WHERE WILL MY VACCINATION INFORMATION BE RECORDED?
The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that you receive the same vaccine when you return for the second dose. For more information about IISs visit: https://www.cdc.gov/vaccines/programs/iis/about.html.

CAN I BE CHARGED AN ADMINISTRATION FEE FOR RECEIPT OF THE COVID-19 VACCINE?
No. At this time, the provider cannot charge you for a vaccine dose and you cannot be charged an out-of-pocket vaccine administration fee or any other fee if only receiving a COVID-19 vaccination. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, Health Resources & Services Administration [HRSA] COVID-19 Uninsured Program for non-insured recipients).

Revised: 10 May 2021

WHERE CAN I REPORT CASES OF SUSPECTED FRAUD?
Individuals becoming aware of any potential violations of the CDC COVID-19
Vaccination Program requirements are encouraged to report them to the Office of the
Inspector General, U.S. Department of Health and Human Services, at
1-800-HHS-TIPS or https://TIPS.HHS.GOV.

WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?
The Countermeasures Injury Compensation Program (CICP) is a federal program that
may help pay for costs of medical care and other specific expenses of certain people
who have been seriously injured by certain medicines or vaccines, including this
vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the
date of receiving the vaccine. To learn more about this program, visit
www.hrsa.gov/cicp/ or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?
The United States FDA has made the Pfizer-BioNTech COVID-19 Vaccine available
under an emergency access mechanism called an EUA. The EUA is supported by a
Secretary of Health and Human Services (HHS) declaration that circumstances exist to
justify the emergency use of drugs and biological products during the COVID-19
pandemic.

The Pfizer-BioNTech COVID-19 Vaccine has not undergone the same type of review as
an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are
met, which includes that there are no adequate, approved, available alternatives. In
addition, the FDA decision is based on the totality of scientific evidence available
showing that the product may be effective to prevent COVID-19 during the COVID-19
pandemic and that the known and potential benefits of the product outweigh the known
and potential risks of the product. All of these criteria must be met to allow for the
product to be used in the treatment of patients during the COVID-19 pandemic.

The EUA for the Pfizer-BioNTech COVID-19 Vaccine is in effect for the duration of the
COVID-19 EUA declaration justifying emergency use of these products, unless
terminated or revoked (after which the products may no longer be used).

Revised: 10 May 2021

Pfizer

Manufactured by
Pfizer Inc., New York, NY 10017

BIONTECH

Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

LAB-1451-5.0
Revised: 10 May 2021

Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

Barcode Date: 05/2021

COVID-19 Vaccine Documentation/Consent Form

Patient Information (Please print legibly)

Last Name: _____ **First Name:** _____ **Middle name:** _____

Date of Birth: _____ **Biological Sex:** ☐ Female ☐ Male ☐ Unknown or Not Reported

Ethnicity: ☐ Non-Hispanic/Latino ☐ Hispanic/Latino (Central/South America, Mexico, Cuba, Puerto Rico, Other) ☐ Unknown/Not Reported

Race 1: ☐ White ☐ Black or African American ☐ Asian ☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander ☐ Other ☐ Unknown or Not Reported

Race 2: ☐ White ☐ Black or African American ☐ Asian ☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander ☐ Other ☐ Unknown or Not Reported

Race 3: ☐ White ☐ Black or African American ☐ Asian ☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander ☐ Other ☐ Unknown or Not Reported

Residential Address: _____ **City:** _____

State: _____ **Zip:** _____ **County:** _____

Phone: _____ **Email:** _____

Screening Questionnaire

COVID-19 Screening Questions

1. In the past two weeks, have you tested positive for COVID-19 or are you currently being monitored for COVID-19? ☐ *Yes* ☐ *No*
2. In the past two weeks, have you had contact with anyone who tested positive for COVID-19? ☐ *Yes* ☐ *No*
3. Do you currently or have you in the past two weeks had a fever, chills, cough, shortness of breath, difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, nausea, vomiting or diarrhea? ☐ *Yes* ☐ *No*
4. Patient temperature: _____ Date: _____

Immunization Screening Questions

1. Are you sick today (cold, fever, acute illness)? ☐ *Yes* ☐ *No*
2. Do you have any allergies to medications, food, a vaccine or latex? ☐ *Yes* ☐ *No*
3. Have you had a serious reaction to a vaccine in the past? ☐ *Yes* ☐ *No*
4. Have you ever had Guillain-Barre syndrome? ☐ *Yes* ☐ *No*
5. Are you pregnant or is there a chance you could become pregnant in the next month? ☐ *Yes* ☐ *No*
6. Are you currently breastfeeding? ☐ *Yes* ☐ *No*
7. Do you have a blood-clotting disorder or are currently taking blood thinners? ☐ *Yes* ☐ *No*
8. Do you have a long-term health problem such as heart disease, lung disease, liver disease, asthma, kidney disease, metabolic disease (e.g., diabetes), anemia or other blood disorder? ☐ *Yes* ☐ *No*
9. Do you have cancer, leukemia, HIV/AIDS, rheumatoid arthritis, ankylosing spondylitis, Crohn's disease or other condition that makes it hard for you to fight infections? ☐ *Yes* ☐ *No*
10. Do you have a weakened immune system or in the past 3 months, taken medications that weaken it such as cortisone, prednisone, other steroids, anti- cancer drugs or radiation treatments? ☐ *Yes* ☐ *No*

4/8/2021

11. During the past year, have you received a transfusion of blood or blood products
    or been given immune (gamma) globulin or an antiviral drug? ☐ *Yes* ☐*No*
12. In the past 4 weeks, have you received any vaccinations or a TB skin test? ☐ *Yes* ☐*No*
13. Do you have a disability? ☐ *Yes* ☐*No*

I have been offered a copy of the COVID-19 Emergency Use Authorization (EUA). I have read, had explained to me, and understand the information in the EUA. I ask that the vaccine be administered to me. I consent to inclusion of this immunization data in the Kansas Immunization Information System (KSWebIZ) for myself.

_____   _____
Signature of Patient   *Date*

_____   _____
Printed Name of Patient   *Date of Birth*

If patient is a minor:

_____   _____
Signature of Parent/Guardian   *Date*

_____
Printed Name of Parent/Guardian

For Office Use Only

Vaccine: COVID-19   **Route:** Intramuscular **Dose:** ____ mL

Manufacturer: ☐ Moderna   ☐ Pfizer   ☐ J&J   ☐ Other _____

Lot Number: _____   **Site:** Deltoid ☐ *Left* ☐ *Right*

Expiration Date: _____   ☐ *Other* _____

Administered By: _____   **Date Given:** _____
                    Signature and Title of Vaccine Administrator

4/8/2021

Formulario de consentimiento/documentación de la vacuna contra el COVID-19

Información del paciente (escriba en letra de molde legible)

Apellido: _____   **Nombre:** _____   **Segundo nombre:** _____

Fecha de nacimiento: _____   **Sexo biológico:** ☐ Femenino ☐ Masculino ☐ Desconocido o no informado

Origen étnico: ☐ No hispano/latino ☐ Hispano/Latino (Centroamérica/Sudamérica, México, Cuba, Puerto Rico, Otro)

☐ Desconocido o no informado

Raza 1: ☐ Blanco ☐ Negro o afroamericano   ☐ Asiático   ☐ Indígena americano o nativo de Alaska

☐ Nativo de Hawái o de otras islas del Pacífico   ☐ Otro   ☐ Desconocido o no informado

Raza 2: ☐ Blanco ☐ Negro o afroamericano   ☐ Asiático   ☐ Indígena americano o nativo de Alaska

☐ Nativo de Hawái o de otras islas del Pacífico   ☐ Otro   ☐ Desconocido o no informado

Raza 3: ☐ Blanco ☐ Negro o afroamericano   ☐ Asiático   ☐ Indígena americano o nativo de Alaska

☐ Nativo de Hawái o de otras islas del Pacífico   ☐ Otro   ☐ Desconocido o no informado

Dirección residencial: _____   **Ciudad:** _____   **Estado:** _____

Código postal: _____   **Condado:** _____

Teléfono: _____   **Email:** _____

Cuestionario de detección

Preguntas de detección de COVID-19

1. En las últimas dos semanas, ¿dio positivo en la prueba de COVID-19 o actualmente lo están controlando para detectar COVID-19? ☐ *Sí* ☐ *No*
2. En las últimas dos semanas, ¿tuvo contacto con alguien que dio positivo por COVID-19? ☐ *Sí* ☐ *No*
3. ¿Tiene actualmente o tuvo en las últimas dos semanas fiebre, escalofríos, tos, falta de aire, dificultad para respirar, fatiga, dolores musculares o corporales, dolor de cabeza, nueva pérdida del gusto u olfato, dolor de garganta, náuseas, vómitos o diarrea? ☐ *Sí* ☐ *No*
4. Temperatura del paciente: _____   Fecha: _____

Preguntas de detección de vacunación

1. ¿Está enfermo hoy (resfrío, fiebre, enfermedad aguda)? ☐ *Sí* ☐ *No*
2. ¿Es alérgico a algún medicamento, comida, vacuna o al látex? ☐ *Sí* ☐ *No*
3. ¿Tuvo una reacción grave a una vacuna en el pasado? ☐ *Sí* ☐ *No*
4. ¿Tuvo alguna vez el síndrome de Guillain-Barré? ☐ *Sí* ☐ *No*
5. ¿Está embarazada o hay posibilidad de que quede embarazada en el próximo mes? ☐ *Sí* ☐ *No*
6. ¿Está amamantando actualmente? ☐ *Sí* ☐ *No*
7. ¿Tiene algún trastorno de coagulación o está tomando anticoagulantes? ☐ *Sí* ☐ *No*
8. ¿Tiene algún problema de salud a largo plazo, como una enfermedad cardíaca, pulmonar, hepática, asma, enfermedad renal, enfermedad metabólica (p. ej., diabetes), anemia u otro trastorno de la sangre? ☐ *Sí* ☐ *No*
9. ¿Tiene cáncer, leucemia, VIH/SIDA, artritis reumatoide, espondilitis anquilosante, enfermedad de Crohn u otra condición que le dificulte combatir las infecciones? ☐ *Sí* ☐ *No*
10. ¿Tiene el sistema inmunitario debilitado o en los últimos 3 meses tomó medicamentos que lo debilitan, como cortisona, prednisona, otros esteroides, medicamentos contra el cáncer o tratamientos de radiación? ☐ *Sí* ☐ *No*
11. Durante el último año, ¿recibió una transfusión de sangre o derivados de la sangre o le dieron inmunoglobulina (gamma) o un medicamento antiviral? ☐ *Sí* ☐ *No*
12. En las últimas 4 semanas, ¿recibió alguna vacuna o una prueba cutánea de tuberculosis? ☐ *Sí* ☐ *No*
13. ¿Tiene alguna discapacidad? ☐ *Sí* ☐ *No*

Me dieron una copia de la Autorización de uso de emergencia (EUA) de COVID-19. Leí, me explicaron y entiendo la información en la EUA. Pido que me administren la vacuna. Doy mi consentimiento para la inclusión de estos datos de vacunación en el Sistema de información de vacunación de Kansas (KSWebIZ) para mí mismo.

_____   _____
Firma del Paciente   *Fecha*

_____   _____
Nombre del paciente en letra de molde   *Fecha de nacimiento*

Si el paciente es menor de edad:

_____   _____
Firma de padre/tutor   *Fecha*

_____
Nombre en letra de molde de padre/tutor

Para uso exclusivo de la oficina

Vacuna: COVID-19   **Vía:**   Intramuscular   **Dosis:** _____ mL

Fabricante: ☐ Moderna   ☐ Pfizer   ☐ J&J   ☐ Otro   _____

Numero de lote: _____   **Sitio:** Deltoides   ☐ *Izquierdo*   ☐ *Derecho*

Fecha de vencimiento: _____   ☐ *Otro*   _____

Administrado por: _____   **Fecha de administración:** _____
Firma y cargo del administrador de vacunas

American Academy
of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®

News Release

Authorization of COVID-19 vaccine for ages 12 and up important step in protecting children during pandemic, says American Academy of Pediatrics

For Release:

5/10/2021

Media Contact:

Lisa Black

630-626-6084

lblack@aap.org

Statement by AAP President Lee Savio Beers, MD, FAAP

"The authorization today by the Food & Drug Administration of the Pfizer-BioNTech COVID-19 vaccine for ages 12 and older is a critically important step in bringing life-saving vaccines to children and adolescents. Our youngest generations have shouldered heavy burdens over the past year, and the vaccine is a hopeful sign that they will be able to begin to experience all the activities that are so important for their health and development.

"We look forward to the discussion by the Advisory Committee on Immunization Practices of the CDC, which will make recommendations about the use of this vaccine in adolescents. Meanwhile, pediatricians stand ready to assist in efforts to administer this and other COVID-19 vaccines.

"It's essential for children to be vaccinated against COVID-19. According to **data** compiled by the AAP and Children's Hospital Association, more than 3.8 million children have tested positive for COVID-19 in the United States since the start of the pandemic. While fewer children than adults have suffered the most severe disease, this is *not* a benign disease in children. Thousands of children have been hospitalized, and hundreds have died. We will soon have a very safe, highly effective vaccine that can prevent so much suffering. I encourage parents to talk with their pediatrician about how to get the vaccine for their adolescents as soon as they are eligible."

##

The American Academy of Pediatrics is an organization of 67,000 primary care pediatricians, pediatric medical subspecialists and pediatric surgical specialists dedicated to the health, safety and well-being of infants, children, adolescents and young adults. For more information, visit ***www.aap.org****.*

FAQ - Vaccine info from American Academy of Pediatrics

Q: What side effects are noted to date with COVID-19 mRNA vaccines (Pfizer-BioNTech and Moderna)?

A: The side effects have been similar to other routine vaccines- sore arm, redness, fatigue, fever, chills, headache, myalgia, and arthralgia. The side effects are temporary and mostly mild or moderate. Side effects may be worse after the second dose in some individuals. Anaphylaxis has been observed following receipt of COVID-19 mRNA vaccines, but this has been rare. A full listing of the side effects is now available on the FDA website and a summary is found in the fact sheet that is provided to everyone who receives the vaccine. The potential for side effects that cause individuals to miss work should also be considered in planning.

Q: Do we need to worry about an increase in Multisystem Inflammatory Syndrome in Children (MIS-C) in kids receiving COVID-19 vaccine?

A: One of the reasons to perform vaccine trials in children is to make sure that they do not have any side effects that are pediatric-specific. Since there are also cases of MIS-A, in young adults, if MIS were to be a problem, we may see it in the larger adult trials. We have not, to date. There is no known biomarker to predict an immune response that leads to MIS-C. It is also possible that protection from COVID-19 by vaccination will also protect against its sequelae, including MIS-C.

Q: What is the safety testing that has been done on COVID-19 vaccines? How do we know it is safe long-term?

A: The safety follow-up for COVID-19 vaccines is essentially the same that it is for all vaccine trials. The expectation for the adult phase 3 trials is 2 years of safety follow-up - longer than for most vaccines during development. It is impossible to know the very long-term safety profile of vaccines that have only been in humans for about 6 months. That said, no vaccines licensed have been found to have an unexpected long-term safety problem, which was found only years or decades after introduction.

Q: Will the vaccine be required for school entry?

A: When a vaccine is shown to be safe and effective in children, health authorities, including the CDC and the AAP, will make recommendations on when and how children should receive the vaccine. However, state governments decide which vaccines are required for school entry within their jurisdictions. Those decisions with respect to COVID-19 vaccine could vary by state and may also be influenced by whether the vaccine is FDA approved vs. administered under an EUA.

Q: Can COVID-19 vaccine be co-administered with other childhood or adolescent immunizations?

A: Administration of the COVID-19 vaccine with other childhood or adolescent immunizations has not yet been studied extensively. There are very few vaccines in which co-administration with other vaccines is problematic. However, given the lack of data, the CDC is currently recommending that COVID-19 vaccine be administered alone with a minimum interval of 14 days before or after administration with any other vaccines. In the case of COVID-19 vaccines that require two doses, this 14-day time period is for each

administration, which means a "blackout" window of 28 days for the Janssen COVID-19 vaccine, 49 days for the Pfizer COVID-19 vaccine and 56 days for the Moderna COVID-19 vaccine.

Q: Do adolescents need special consent or assent to receive the COVID-19 vaccine?

A: Adolescents aged ≥ 16 years do not need special consent to receive vaccine under an EUA. However, assent is required. Health care providers administering the vaccine should inform vaccine recipients the following: (1) FDA has authorized emergency use of the vaccine (2) known and potential risks and benefits related to emergency use (3) that they have the option to accept or refuse the product and (4) be informed of any available alternatives to the product and their known risks and benefits. Each recipient should receive a fact sheet that includes essential information about the vaccine. The fact sheets for health care professionals administering the vaccine as well as recipients were approved as part of the authorization and are available from the Pfizer and FDA websites:

Q: How quickly after immunization does the vaccine protect the recipient, and how long does immunity last?

A: For the mRNA vaccines developed by Pfizer-BioNTech and Moderna, studies reported vaccine efficacy at 7 to 14 days after the second dose, which is likely how long it takes to get very high levels of neutralizing antibody. Studies to date have shown that both mRNA vaccines maintain high efficacy levels over a six-month period (eg. 91% Pfizer-BioNTech, 90% Moderna). More research will be conducted to monitor vaccine efficacy over time. For the Janssen viral vector vaccine, one dose is recommended, and immunity is shown 2 to 4 weeks after vaccination.

Q: What do we know about the new SARS-CoV-2 variants?

A: Multiple variants of SARS-CoV2 have been documented in the United States and globally during this pandemic. New variants have been identified in the United Kingdom (UK), South Africa, and Brazil, and some are reported to spread more rapidly than existing strains. Information about these variants is rapidly emerging. These variants seem to spread more easily and quickly than other variants, which may lead to more cases of COVID-19. Viruses often mutate, or develop small changes, as they reproduce and move through a population. Public health officials are monitoring this closely and continued surveillance is being conducted. Experts believe that the COVID-19 vaccine will provide protection against the new variants that have been reported to date.

Revised: 4/29/2021

The Science Behind the COVID-19 Vaccine: Parent FAQs

As a parent, you probably have plenty of questions about COVID-19 vaccines. Right now, they're authorized for teens age 16 and older. However, the vaccines are expected to be available for children age 12 and up soon. Here are answers to some of the most common questions families have about COVID-19 vaccines.

How does the COVID-19 vaccine work?

The COVID-19 vaccine works similarly to other vaccines your child has had. Germs such as SARS-CoV-2, the virus that causes COVID-19, invade and multiply inside the body. The vaccine stops this by helping the immune system make special proteins call antibodies to fight the virus. After vaccination, your child has less of a chance of getting COVID-19. And if they do get infected with the virus, they may not' be as sick as they would without the vaccine.

What are the types of vaccines?

Three different vaccines were given emergency use authorization by the U.S. Food and Drug Administration (FDA) so far. Two require two doses (Pfizer and Moderna), and one involves a single shot (Johnson & Johnson).

Distribution of the one-shot vaccine was temporarily paused to look for possible ties to rare but serious blood clots reported during the vaccine's safety monitoring process. The FDA lifted (https://www.fda.gov/news-events/press-announcements/fda-and-cdc-lift-recommended-pause-johnson-johnson-janssen-covid-19-vaccine-use-following-thorough)the pause when data confirmed the chance of developing the rare clots with the vaccine is extremely low, but continues to monitor the risk.

The COVID-19 vaccines that require two doses are both messenger ribonucleic acid (mRNA) vaccines. The other was developed as a "viral vector" vaccine. They all have the same result — protecting people from COVID-19—but their delivery systems are a bit different.

How RNA and viral vector vaccines different?

COVID-19 mRNA vaccines carry instructions to our cells to produce harmless pieces of "spike" protein found on SARS-CoV-2. This triggers an immune system response that the body remembers if the virus ever invades.

Although this technology has been studied for decades, widespread use of mRNA vaccines is new. They don't use the live coronavirus that causes COVID-19. The mRNA in the vaccine gets into the cells where the shot is given. Then it gives the cells instructions on how to create a piece of protein that is found on the virus that causes COVID-19.

Once the protein is created, your immune system identifies it as a foreign molecule. body. The immune process starts, making antibodies that attach to the protein. These antibodies then protect you from getting COVID-19.

Viral vector vaccines, like the mRNA vaccines, also give instructions to your immune cells. Instead of carrying the instructions to your cells on a fat bubble, as with the mRNA vaccine, they are carried in a harmless virus (not the coronavirus that causes COVID-19).

The same process happens as with the mRNA vaccine—the cells create the protein that's found on the virus that causes COVID-19, the immune system makes antibodies to fight it, and you're protected from getting COVID-19.

How do we know COVID-19 vaccines are safe for kids?

Before getting FDA authorization, clinical trials showed COVID-19 vaccines to be remarkably safe and effective for adults and teens age 16 and up. Trials for each of the vaccines involved tens of thousands of volunteers. Back to Top

Based on clinical trial results for younger adolescents, one of the vaccine makers has now asked the FDA to extend emergency use authorization for children as young as age 12. And clinical trials are starting for children as young as six months old.

The vaccines continue to be monitored very closely. In fact, the Centers for Disease Control and Prevention (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html) (CDC) say that COVID-19 vaccines will have "the most intensive safety monitoring in U.S. history."

How effective are the vaccines?

Research shows that all of the COVID-19 vaccines are highly effective at stopping people from getting COVID-19. The vaccines also help prevent serious illness, hospitalization, and death in those who get COVID- 19.

Scientists don't know how long immunity from the vaccine will protect people. This will become clearer in the future.

How long does it take for the vaccines to create immunity?

It takes around 2 weeks after getting the second dose of the mRNA vaccines for your body to build up an immunity to the virus that causes COVID-19. For the one-dose vaccine, building up immunity takes 2 to 4 weeks.

Do mRNA vaccines change your DNA?

No, the mRNA actually doesn't interact with your DNA at all. DNA is your genetic material and it's stored in the nucleus of a cell. The mRNA in the vaccines doesn't get into the nucleus. And once your immune cells have used the instructions, they break down the mRNA and discard it.

Which vaccine should my child get?

Currently, one of the two-dose vaccines (Pfizer) is approved for teens who are 16 to 17 years old. Anyone who is 18 or older should get whichever vaccine is available to them first. This is especially important now with the rise in cases caused by the variant strains of the virus, which seem to be more contagious and continue to spread at alarming rates here in the US and globally. COVID-19 vaccines are free (https://www.hhs.gov/sites/default/files/uninsured-patient-covid-services-poster.pdf), whether or not you have health insurance.

What about side effects of the vaccine?

We're still waiting for more detailed information on side effects in kids under the age of 16 years old. Some people don't have any side effects at all. But for those who are 16 or older, the most common side effects that have been reported include:

- Pain, redness, and swelling where the injection was given
- Fever
- Chills
- Headache
- Fatigue
- Nausea
- Pain in the muscles

While also rare, some people have had serious allergic reactions to the COVID-19 vaccine. This is why you'll need to wait for 15 to 30 minutes after you have a vaccination. If you happen to be one of the few people who has an allergic reaction, there are medications to quickly treat it.

As for long-term side effects, the CDC says this is unlikely (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html). We have years of research and monitoring on other vaccinations that show side effects almost always happen within six weeks of getting a vaccine.

Is it safe to get a vaccine if I'm pregnant or breastfeeding?

Right now, there's no evidence that getting a COVID-19 vaccine causes any safety concerns for pregnant or breastfeeding women. The American College of Obstetricians and Gynecologists (ACOG) recommends that pregnant and breastfeeding women should be offered the vaccine when they're eligible.

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Were fetal cells used in the COVID-19 vaccine's development?

None of the vaccines contain fetal cells. All of the vaccines have used fetal cell lines at some point, but there is a difference between fetal cells and fetal cell lines.

Fetal cell lines have been grown in labs since the 1960s. These cells have multiplied, creating generations of fetal cell lines. This means that the cells we have today no longer contain fetal tissue. Several religious groups and bioethics institutes have issued statements and guidance about the COVID-19 vaccines. For instance, the U.S. Conference of Catholic Bishops (https://www.usccb.org/moral-considerations-covid-vaccines) states that getting vaccinated is morally justifiable given the circumstances. The Charlotte Lozier Institute (https://lozierinstitute.org/) has information available for those who want to learn more about this topic.

More information

- Ask the Pediatrician: When can children get the COVID-19 vaccine? (/English/tips-tools/ask-the-pediatrician/Pages/when-can-children-get-the-COVID-19-vaccine.aspx)
- Ask the Pediatrician: When will it be safe for my kids to hug their grandparents after they get the COVID-19 vaccine? (/English/tips-tools/ask-the-pediatrician/Pages/hug-their-grandparents-once-they-get-the-vaccine.aspx)
- Understanding How COVID-19 Vaccines Work (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/how-they-work.html) (Centers for Disease Control and Prevention)

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COVID-19 vaccination is a safer way to build protection

- Getting the virus that causes COVID-19 may offer some natural protection, known as an antibody or immune. But experts don't know how long this protection lasts.

- The risk of severe illness and death from COVID-19 far outweighs any benefits of natural immunity.

- COVID-19 vaccination will help protect you by building immunity without the risk of severe illness.

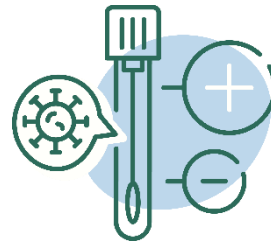# Key facts about COVID-19 vaccination

Getting vaccinated can help prevent getting sick with COVID-19

People who have already gotten sick with COVID-19 may still benefit from getting vaccinated

COVID-19 vaccines <u>cannot</u> give you COVID-19

COVID-19 vaccines will not cause you to test positive on COVID-19 <u>viral</u> tests*

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/about-vaccines/vaccine-myths.html

*https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html

ROLL UP YOUR SLEEVES, KANSAS!
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