Immunization Service Provider Call

October 2023

Please place your name, and provider in the chat.

OKLAHOMA
State Department of Health

Agenda

- State Data / COVID Administration Guidance
- COVID-19 Vaccine Ordering Update
- Vaccine Storage and Handling
- Vaccine Ordering & Distribution
- OSIIS Updates
- Guest Speaker

  Lauren Speer, BSN, RN.

  Immunization and Communicable Disease Nurse Consultant, Nursing Services

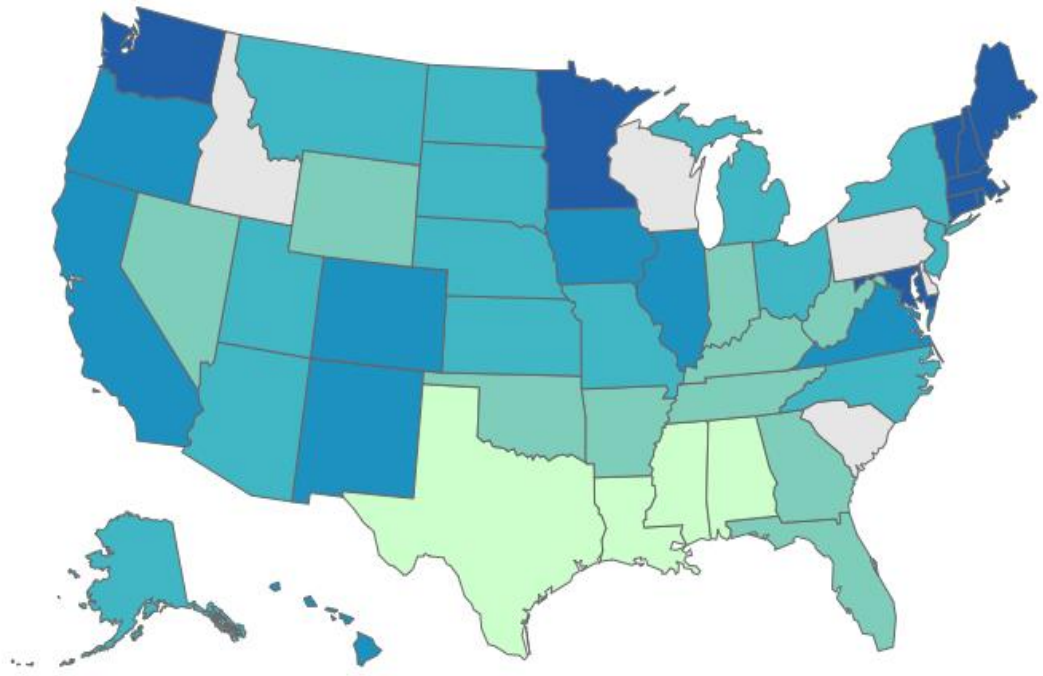
  - Flu and RSV
- Looking Forward

COVID-19 Vaccine State Data & Administration Guidance

Rishu Garg, Adult Vaccine Coordinator

OKLAHOMA State Department of Health

Percent of the Total Population Who Are Up to Date with COVID-19 Vaccines, (CDC)



Oklahoma: 12.5% of Population
493,059
Female: 13.6% Male: 11.3%

UTD Break Points	0 - 9.9%		10.0 - 14.9%		15.0 - 19.9%		20.0 - 24.9%		25.0% +	
Location	Percent	Count	Percent	Count	Percent	Count	Percent	Count	Percent	Count
Vermont									35.3	220,451
District of Columbia									33.9	239,492
Maine									32.1	431,740
Massachusetts									32.0	2,202,523
Minnesota									28.0	1,578,075
Washington									27.0	2,058,666
Rhode Island									26.5	280,343
Connecticut									26.1	932,244
Maryland									25.1	1,518,596
New Hampshire									25.0	340,323
Hawaii							23.8	336,778		
Oregon							23.6	997,237		
New Mexico							23.0	483,312		
Colorado							22.9	1,317,927		
Virginia							21.8	1,864,791		
California							21.6	8,526,317		
Illinois							21.0	2,663,126		
Iowa							20.6	649,800		

People who are up to date: Adults and children aged 6 years and older are up to date with COVID-19 vaccines if they got a bivalent (updated) COVID-19 vaccine. Children 6 months through 5 years of age who received the Pfizer-BioNTech COVID-19 vaccine are up to date if: They are 6 months to 4 years of age and got at least 3 COVID-19 vaccine doses, including at least one bivalent (updated) COVID-19 vaccine dose or They are 5 years of age and got at least 1 bivalent (updated) COVID-19 vaccine dose. Children 6 months through 5 years of age who got the Moderna COVID-19 vaccine are up to date if they got at least two Moderna COVID-19 vaccine doses, including at least one bivalent (updated) COVID-19 vaccine dose; CDC uses US Census estimates for the total populations within each specified demographic group regardless of prior vaccination

Updated (2023-2024 Formula) Interim Clinical Considerations for Use of COVID-19 Vaccines

Summary of recent changes (last updated September 15, 2023)

Recommendations for use of the 2023–2024 formulations of Moderna COVID-19 Vaccine and Pfizer-BioNTech COVID-19 Vaccine:

- Everyone ages 5 years and older is recommended to receive 1 dose of updated (2023–2024 Formula) mRNA COVID-19 vaccine
- Children ages 6 months–4 years
  - Initial vaccination: should receive either 2 doses of updated (2023–2024 Formula) Moderna or 3 doses of updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 vaccine
  - Received previous mRNA doses: need 1 or 2 doses of updated (2023–2024 Formula) Moderna or updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 vaccine, depending on the number of prior doses
- People who are moderately or severely immunocompromised
  - Initial vaccination: should receive a 3-dose series of updated (2023–2024 Formula) Moderna or updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 vaccine
  - Received previous mRNA doses: need 1 or 2 doses of updated (2023–2024 Formula) Moderna or updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 vaccine, depending on the number of prior doses
  - May receive 1 or more additional updated (2023–2024 Formula) mRNA COVID-19 vaccine doses
- **Bivalent mRNA COVID-19 vaccines and Original Monovalent Novavax vaccines are no longer recommended in the United States**

•Updated guidance for COVID-19 vaccination and myocarditis or pericarditis
•Updated guidance for COVID-19 vaccination and Multisystem Inflammatory Syndrome (MIS) in children (MIS-C) and in adults (MIS-A)
•Reorganization and consolidation of sections on contraindications and precautions, including allergic reactions to COVID-19 vaccines

CDC Clinical Considerations

Reference Materials

•Interim COVID-19 Immunization Schedule (Updated 9/22/2023)
•COVID-19 Vaccination Recommendations Infographic (Updated 9/20/2023)
•COVID-19 Vaccination Recommendations Infographic (Immunocompromised) (Updated 9/20/2023)
•COVID-19 Vaccine Product Information (Updated 9/25/2023)

FDA Updated Novavax COVID-19 Vaccine (2023-2024 Formula) Authorization

as of October 5th, 2023

➢ **On October 3, 2023, the FDA amended the EUA of Novavax COVID-19 vaccine to include the 2023-2024 formula.**

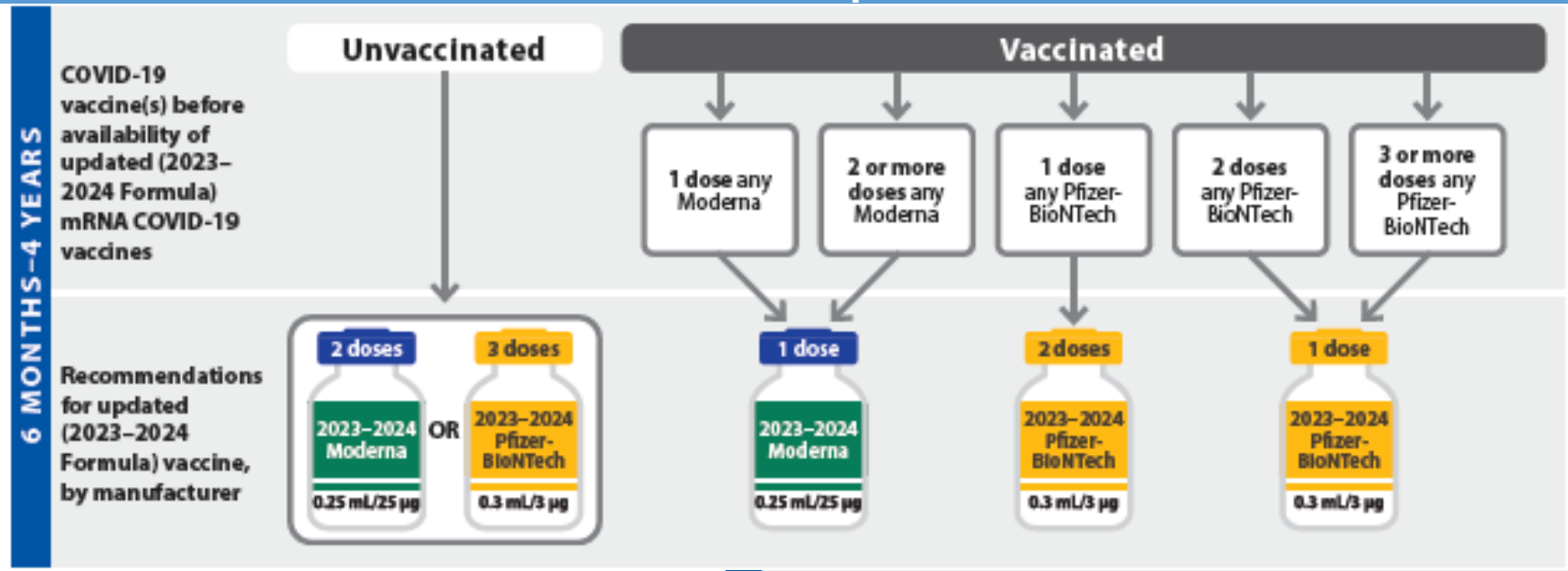
- The Novavax COVID-19 Vaccine, Adjuvanted, a monovalent vaccine, has been updated to include the spike protein from the SARS-CoV-2 Omicron variant lineage XBB.1.5 (2023-2024 formula).
- Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) is authorized for use in individuals 12 years of age and older.
  - The updated authorization details are available on the FDA website.
  - We will share updated clinical and operational guidance and ordering details as it becomes available.

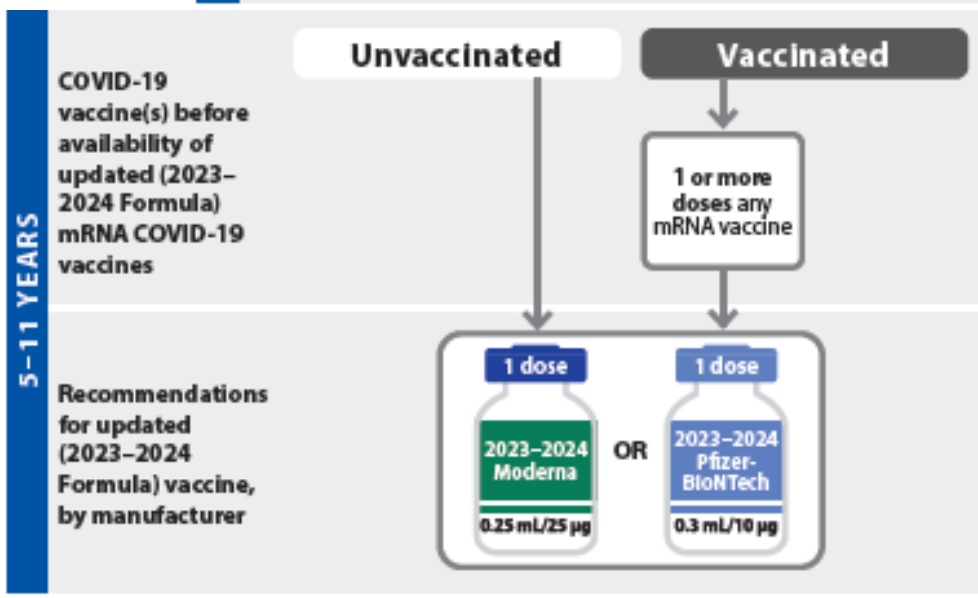
➢ **The Novavax COVID-19 Vaccine, Adjuvanted (Original monovalent) is no longer authorized.**

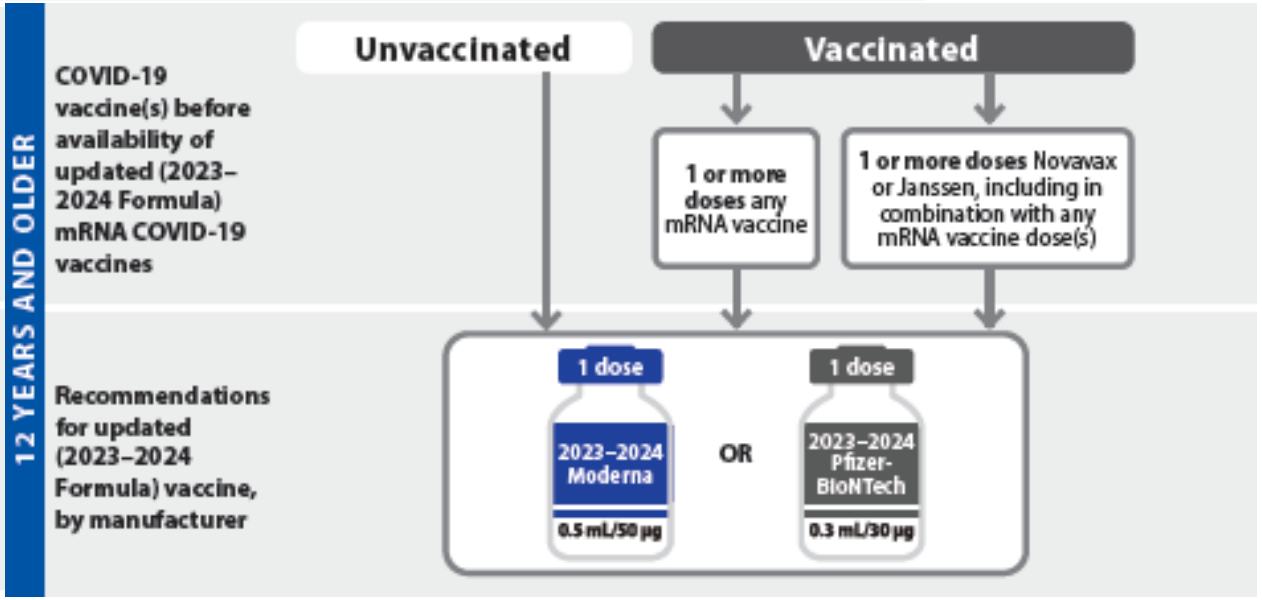
- As part of the FDA's actions, the Novavax COVID-19 Original Monovalent Vaccine is no longer authorized for use in the United States. To minimize the risk of vaccine administration errors, providers should:
  - Remove all Original monovalent Novavax COVID-19 vaccines from storage units immediately, even if they are not expired.
  - Once all inventory is fully accounted for, ***zero out all original monovalent Novavax COVID-19*** vaccines from your clinic's available vaccine inventory on hand in OSIIS.
  - Dispose of all original monovalent Novavax COVID-19 vaccine vials in accordance with local, state, and federal regulations.
  - Report all disposed inventory as wastage.

Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) Fact Sheet

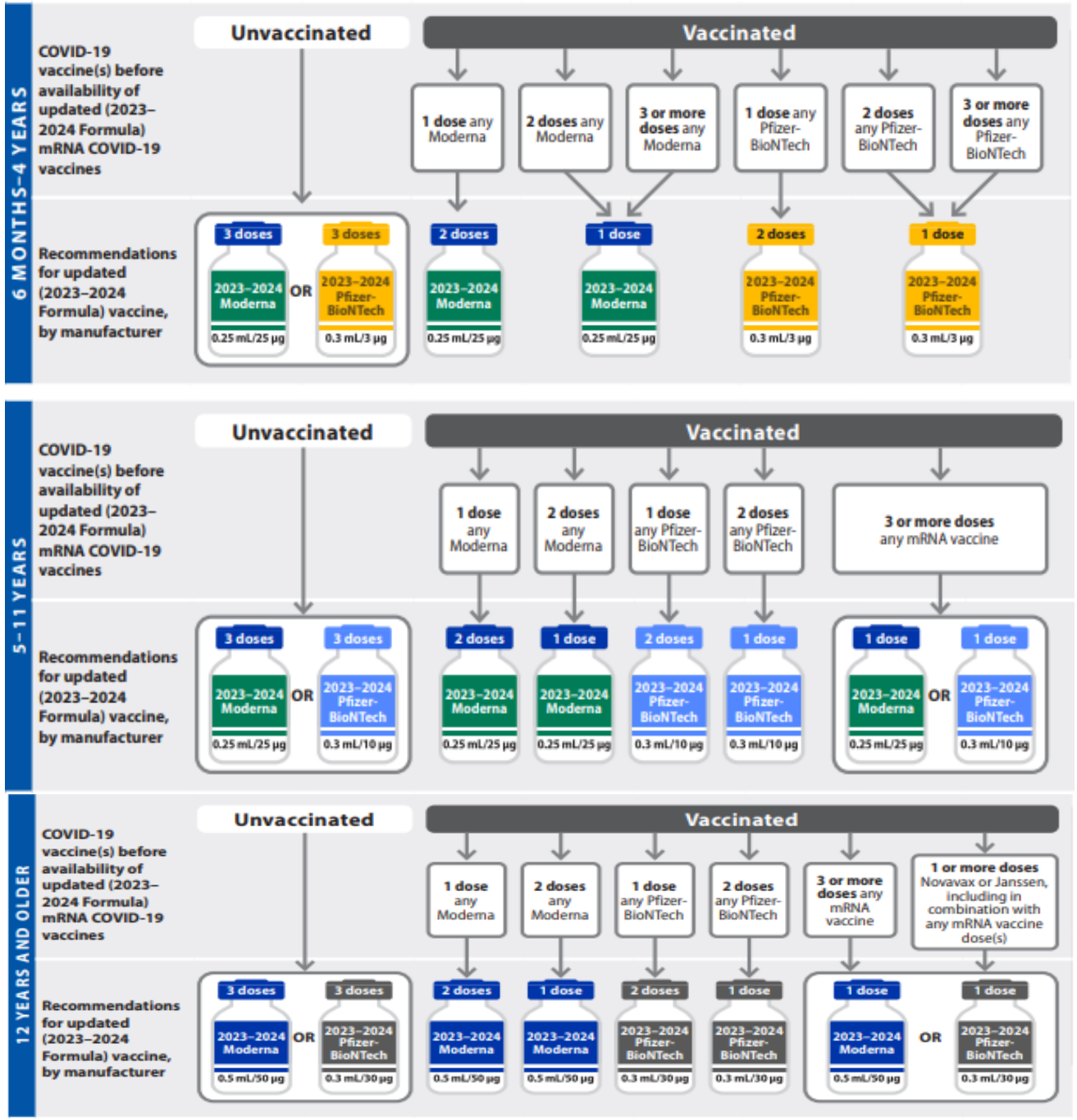
Recommended updated (2023–2024 Formula) mRNA COVID-19 vaccines for people who are NOT moderately or severely immunocompromised*†







Recommended updated (2023–2024 Formula) mRNA COVID-19 vaccines for people who ARE moderately or severely immunocompromised*†



‡The FDA EUA provides that children who transition from age 4 years to age 5 years during the Pfizer-BioNTech vaccination series complete the 3-dose series with updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 Vaccine for ages 6 months–4 years, 0.3 mL/3 ug (yellow cap; yellow label).
The FDA EUA provides that children who transition from age 4 years to age 5 years during the Moderna vaccination series complete the 2-dose series; *there is no dosage change.*

The COVID-19 vaccination schedule for people who are moderately or severely immunocompromised is detailed in Table 2.

Updated COVID-19 (2023-2024) Vaccine Formulations

Two types of COVID-19 vaccines are available for use in the United States:

- mRNA vaccines
  - Moderna COVID-19 Vaccine (2023–2024 Formula) is authorized for children ages 6 months–11 years; SPIKEVAX is the licensed Moderna product for people ages 12 years and older. These vaccines are hereafter referred to as updated (2023–2024 Formula) Moderna COVID-19 Vaccine.
  - Pfizer-BioNTech COVID-19 Vaccine (2023–2024 Formula) is authorized for children ages 6 months–11 years; COMIRNATY is the licensed Pfizer-BioNTech product for people ages 12 years and older. These vaccines are hereafter referred to as updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 Vaccine.
- Protein subunit vaccine
  - Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) is authorized for use in individuals 12 years of age and older.

COVID-19 vaccine composition

- Moderna and Pfizer-BioNTech COVID-19 vaccines: The 2023–2024 formulation has been updated to a monovalent vaccine based on the Omicron XBB.1.5 sublineage of SARS-CoV-2. The bivalent formulation (Original and Omicron BA.4/BA.5) should no longer be used.
- Novavax COVID-19 Vaccine: the 2023-2024 formulation has been updated to include the spike protein from the SARS-CoV-2 Omicron variant lineage XBB.1.5. The Original Monovalent formulation should no longer be used.

COVID-19 vaccine-specific package inserts and FDA fact sheets' and U.S. COVID-19 Vaccine Product Information

can be consulted for a full list of ingredients and information on the conditions of use, storage and handling, preparation, and administration procedures.

COMIRNATY and Pfizer-BioNtech (2023-2024) Covid-19 Vaccines

Age Group	12 years and older	12 years and older*	5 through 11 years	6 months through 4 years
Cap Color & Label Border	Gray 	N/A 	Blue 	Yellow 
Dilution	DO NOT DILUTE	New! Prefilled Syringe*	DO NOT DILUTE	DILUTE BEFORE USE Diluent amount per vial: 1.1 mL†
Number of Doses	Single Dose Vial	Single Dose	Single Dose Vial	3 doses per vial
Dose	30 mcg	30 mcg	10 mcg	3 mcg
Dose Volume	0.3 mL	0.3 mL	0.3 mL	0.3 mL

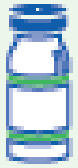
Pfizer Vaccines - At a Glance - CDC

COMIRNATY Package Insert

EUA Fact Sheet Pfizer-BioNtech COVID-19 Vaccine 6m-11yrs

SPIKEVAX Moderna COVID-19 Vaccine (2023-2024) Formulations

Ages	6 months through 4 years	12 years and older	12 years and older
Supplied in:	Single-dose vial (SDV)	Single-dose vial (SDV)	Manufacturer-filled syringe (MFS)
Cap and/or label color:	Dark blue cap and green label	Dark blue cap and blue label	N/A



Ages: 6 months through 11 years

Single-dose vial:
Dark blue cap and green label

Ages: 12 years and older

Single dose vial:
Dark blue cap and blue label

Manufacturer-filled syringe

Recipient's Age	Dosage	Route	Needle gauge and length	Site
6 months through 11 years of age	0.25 mL/25 *ug*	IM injection	22–25 gauge, 1"*	**6 months–2 years of age:** Vastus lateralis muscle in the anterolateral thigh†
				3–11 years of age: Deltoid muscle in the upper arm‡
12 years of age and older	0.5 mL/50 *ug*	IM injection	22–25 gauge, 1–1.5"*	Deltoid muscle in the upper arm‡

Additional Guidance: [Moderna COVID-10 Vaccine | FDA](#) | [Spikevax | FDA](#) | [Moderna Vaccines | Modernaatx.com](#)

[Updated 2023-2024 Moderna Covid Vaccines At a Glance - CDC](#)

Timing, spacing, age transitions

4-Day grace period

- Doses administered up to 4 days before the minimum interval or age, known as the 4-day grace period, are considered valid. If a dose is administered prior to the 4-day grace period, see Appendix B. Doses administered at any time after the recommended interval are valid.

Transitioning from a younger to older age group

- In general, CDC recommends that people receive the age-appropriate vaccine product and dosage based on their age on the day of vaccination (Table 1 and Table 2).
- If a person moves to an older age group between vaccine doses, they should receive the vaccine product and dosage for the older age group for all subsequent doses with one exception:
- The FDA EUA provides that children who transition from age 4 years to age 5 years during the Pfizer-BioNTech COVID-19 vaccination series complete the 3-dose series with updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 Vaccine for ages 6 months–4 years, 0.3 mL/3 ug (yellow cap; yellow label).
- In addition, the FDA EUA provides that children who transition from age 4 years to age 5 years during the Moderna vaccination series complete the 2-dose series; there is no dosage change.

Interchangeability of COVID-19 vaccines

- Children ages 6 months–4 years should receive all doses of COVID-19 vaccine from the same manufacturer; this includes children who are moderately or severely immunocompromised and those who are not. People ages 5 years and older who are moderately or severely immunocompromised should receive a 3-dose initial vaccination series using vaccines from the same manufacturer.
- In the following exceptional situations, a different age-appropriate COVID-19 vaccine may be administered:
  - Same vaccine not available
  - Previous dose unknown
  - Person would otherwise not complete the vaccination series
  - Person starts but unable to complete a vaccination series with the same COVID-19 vaccine due to a contraindication
- A Vaccine Adverse Event Reporting System (VAERS) report is not indicated for these exceptional situations.
- For people who receive 1 Moderna and 1 Pfizer-BioNTech vaccine dose, complete the initial vaccination series as follows:
  - Children ages 6 months–4 years who are not moderately or severely immunocompromised should follow a 3-dose schedule. A third dose of either updated (2023–2024 Formula) Moderna vaccine or updated (2023–2024 Formula) Pfizer-BioNTech vaccine should be administered at least 8 weeks after the second dose.
  - People ages 6 months and older who are moderately or severely immunocompromised should follow the recommended 3-dose schedule. A third dose of either updated (2023–2024 Formula) Moderna vaccine or updated (2023–2024 Formula) Pfizer-BioNTech vaccine should be administered as follows:
  - Ages 6 months–4 years: at least 8 weeks after the second dose
  - Ages 5 years and older: at least 4 weeks after the second dose

The COVID vaccination schedules for People who are **not** moderately or severely immunocompromised and People who are moderately or severely immunocompromised should be consulted for age-specific information; see Appendix B for recommended actions following interchangeability-related COVID-19 vaccine administration errors or deviations.

Bridge Access Program for COVID-19 Vaccines and Treatments

- Provide access to only COVID-19 vaccines and treatments for eligible populations, under and uninsured individuals 19 years of age and older
- The program is temporary, beginning in Fall of 2023 and scheduled to end on Dec 31st, 2024
- Almost 25-30 million uninsured and underinsured adults are qualified to participate in the program
- Limited doses of COVID-19 vaccines available to state immunization awardees, local health departments (LHDs) and associated clinics, eligible FQHCs, Rural Health Centers, and Indian Health Service and Tribal Providers.
- Participating Pharmacies: CVS, Walgreen's and e-True North
- Request for further information: bridgeaccess@health.ok.gov

COVID- 19 Vaccine Ordering Updates

Margaret Archer, MPH, and Muhammad Khalil, BSM
Covid-19 Vaccine Ordering Team

OKLAHOMA State Department of Health

COVID-19 Vaccine Ordering in OSIIS

- OSIIS offers 5 COVID-19 vaccine formulations across all age groups.
- Updates to the ordering process
  - When placing orders for COMIRNATY (Pfizer) 12+ and Spikevax (Moderna) 12+, be sure to select the appropriate intent (ADULT or PED). This will determine the funding source used to purchase the vaccine.
  - Providers no longer have the option to opt-out of receiving ancillary kits.
  - Providers can no longer request dose amounts less than the minimum dose requirements for direct shipment.

As a reminder, please remember to regularly check the OSIIS homepage for news updates related to COVID-19 Vaccines.

COVID-19 Vaccines available in OSIIS

CVX	Name on OSIIS ordering page	NDC	Manufacturer	Doses per Package
308	Pfizer-BT 2023-2024 (10 x 3 dose vials) 6m-4yrs	59267-4315-02	PFIZER, INC.	30
309	COMIRNATY 2023-2024 (10 x 0.3mL vials) 12+ yrs	00069-2362-10	PFIZER, INC.	10
310	Pfizer-BT 2023-2024 (10 x 0.3mL sdv vials) 5-11 yr	59267-4331-02	PFIZER, INC.	10
311	Moderna 2023-2024 (10 x 0.25mL sdv vials) 6m-11y	80777-0287-92	MODERNA	10
312	Spikevax 2023-2024 (10 x 0.5mL sdv vials) 12+ yrs	80777-0102-95	MODERNA	10

The updated Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula), will be available in OSIIS once the allocation is received.

COVID-19 Vaccine for Children Ordering in OSIIS

- COVID-19 Vaccines that are ordered with Pediatric intent are funded by the Vaccines for Children Program (VFC).
  - *Please ensure that these vaccines are administered only to VFC-eligible children.*
- More information about VFC eligibility can be found here: CDC VFC Program Eligibility

CVX	Name	NDC	Manufacturer Code	Manufacturer	Cost per Package	Doses per Package	Intent
308	Pfizer-BT 2023-2024 (10 x 3 dose vials) 6m-4yrs	59267-4315-02	PFR	PFIZER, INC.	$0.30	30	PEDIATRIC
309	COMIRNATY 2023-2024 (10 x 0.3mL vials) 12+ yrs	00069-2362-10	PFR	PFIZER, INC.	$0.10	10	PEDIATRIC
310	Pfizer-BT 2023-2024 (10 x 0.3mL sdv vials) 5-11 yr	59267-4331-02	PFR	PFIZER, INC.	$0.10	10	PEDIATRIC
311	Moderna 2023-2024 (10 x 0.25mL sdv vials) 6m-11y	80777-0287-92	MOD	MODERNA	$0.10	10	PEDIATRIC
312	Spikevax 2023-2024 (10 x 0.5mL sdv vials) 12+ yrs	80777-0102-95	MOD	MODERNA	$0.10	10	PEDIATRIC

Vaccine Storage and Handling

Sonja Claborn LPN,
Immunization Field Consultant

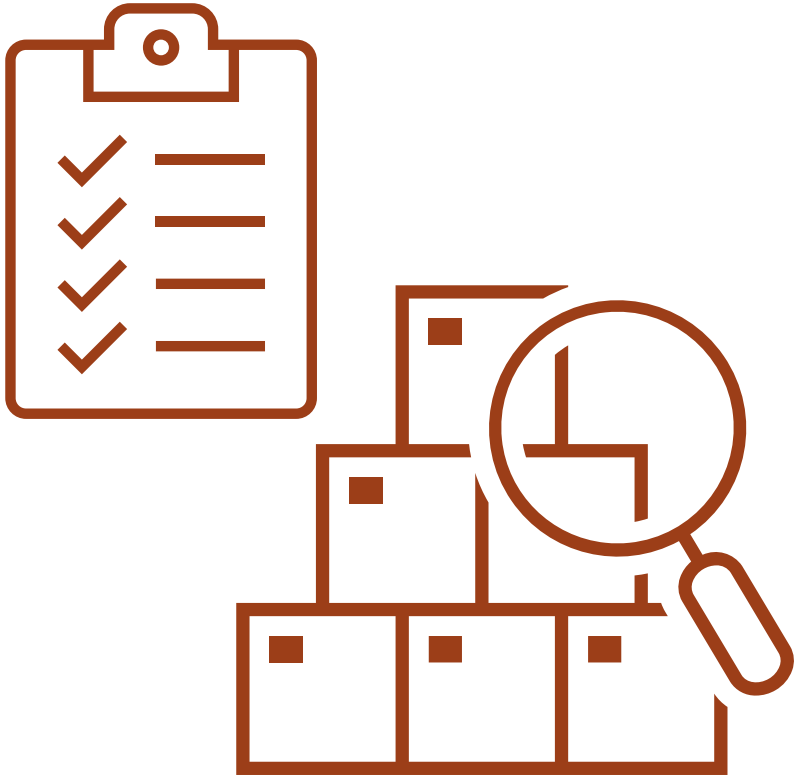
OKLAHOMA
State Department
of Health

Best Practices for Inventory Management

- To reduce waste, providers should be aware of vaccines in their inventory that are nearing expiration dates and prioritize their administration.

- Providers should enroll in the CDC Code Management Service to access the most up-to-date Expiration Information for all Vaccines.
  - Vaccine Lot Number and Expiration Date Webpage
  - Click the "Register" button in the upper right-hand corner to complete the registration form to request access.

- Moderna, Novavax, and Pfizer Vaccine Expiration Lookup & Reference Information:
  - Moderna Vial Expiration Data Look Up Tool
  - Pfizer-BioNTech Covid-19 Lot Expiry Tool
  - Novavax Expiry Date Checker Tool



Covid Vaccine Inventory Clean Up : Unauthorized Vaccines

As of September 13th, 2023, the bivalent Moderna and Pfizer-BioNTech COVID-19 vaccines are no longer authorized for use.
As of October 3rd, 2023, the Novavax COVID-19 Vaccine, Adjuvanted (Original monovalent) is no longer authorized.

To minimize the risk of vaccine administration errors, providers should:

- Remove all bivalent mRNA *and* original monovalent Novavax COVID-19 vaccines from storage units *immediately*, even if they have not expired.
- Once all inventory is fully accounted for, ***zero out all bivalent mRNA and original monovalent Novavax*** vaccines from your clinic's available vaccine inventory on hand in OSIIS.
- Dispose of all bivalent mRNA and original monovalent Novavax COVID-19 vaccine vials in accordance with local, state, and federal regulations.
- Report all disposed inventory as wastage in OSIIS.
- Refer to the tip sheet for further guidance: COVID-19 Vaccine Cleanup -Inventory Adjustment- Report Wastage OSIIS TipSheet.docx

The table below lists COVID-19 vaccines that *must be removed* from your inventory.

Manufacturer	Presentation	Unit of Sale NDC
Moderna TX Inc.	MDV5; 10-pack	80777-0282-99
Moderna TX Inc.	Ped 6m-5y; MDV2; 10pk	80777-0283-99
Pfizer Inc.	MDV6; 10-pack	59267-0304-02
Pfizer Inc.	SDV; 10pk	59267-1404-02
Pfizer Inc.	Ped 5y-11y; MDV10; 10pk	59267-0565-02
Pfizer Inc.	Ped 6m-4y; MDV10; 10pk	59267-0609-02
Novavax	10 x 2.5mL Multi-Dose Vial	80631-0102-10

If you have any questions or concerns, please reach out to Margaret.Archer@health.ok.gov

Covid Vaccine Wastage

- COVID-19 vaccines received as a part of CDC's routine programs- VFC, 317, and Bridge access program will need to be returned to McKesson once they are expired or spoiled.
- Only non-viable vaccines cannot be returned to McKesson, which includes broken vials/syringes, vaccine drawn into a syringe but not administered are considered wastage.
- COVID-19 vaccine program requirements include reporting wastage (unused, open, spoiled, or expired) into OSIIS. Please follow the Wastage tip sheet to report COVID-19 vaccine wastage.
- After recording, the vaccine must be disposed of in accordance with Oklahoma regulations and processes to dispose of regulated medical waste.

Operational Summary for Identifying, Disposing, and Reporting COVID-19 Vaccine Wastage | CDC

Comirnaty and Pfizer-BioNTech (2023-2024) Storage and Handling

Ages	6 months through 4 years	5 through 11 years	12 years and older	12 years and older
Supplied in:	3-dose multiple-dose vial (MDV)	Single-dose vial (SDV)	Single-dose vial (SDV)	Manufacturer-filled syringe (MFS)
Cap and/or label color:	Yellow cap and yellow label	Blue cap and blue label	Gray cap and gray label	N/A
Storage temperature before puncture	**Between:** ▪ -90°C and -60°C (-130°F and -76°F) until the expiration date ▪ 2°C and 8°C (36°F and 46°F) for up to 10 weeks ▪ 8°C and 25°C (46°F and 77°F) for up to 12 hours prior to the first puncture or use. **Do not store between -25°C and -15°C (-13°F and 5°F).** **NOTE:** The beyond-use date (10 weeks) replaces the manufacturer's expiration date but **NEVER** extends it. Always use the earliest date. Do NOT use vaccine after the expiration date or beyond-use date.			
Thawing frozen vaccine	**Between:** ▪ 2°C and 8°C (36°F and 46°F) for up to 2 hours OR ▪ Up to 25°C (77°F) for 30 minutes			**Between:** ▪ 2°C and 8°C (36°F and 46°F) for 2 hours (preferred method) OR ▪ Up to 25°C (77°F) for 60 minutes **Note:** Individual syringes thawed at room temperature that are not used immediately must be used within 4 hours or discarded.

Additional guidance: CDC Vaccine Storage and Handling Toolkit | Pfizer BioNtech COVID Vaccine | FDA | Comirnaty | FDA | https://www.cvdvaccine.com/ Comirnaty Package Insert | Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) Fact Sheet

Spikevax and Moderna COVID-19 (2023-2024) Storage and Handling

Ages	6 months through 4 years	12 years and older	12 years and older
Supplied in:	Single-dose vial (SDV)	Single-dose vial (SDV)	Manufacturer-filled syringe (MFS)
Cap and/or label color:	Dark blue cap and green label	Dark blue cap and blue label	N/A
Storage temperature before puncture	**Between:** ▪ -50°C and -15°C (-58°F and 5°F) until the expiration date ▪ 2°C and 8°C (36°F and 46°F) for up to 30 days ▪ 8°C and 25°C (46°F and 77°F) for a total of 24 hours. Discard vial or syringe and unused vaccine after 24 hours. **NOTE:** The beyond-use date (30 days) replaces the manufacturer's expiration date but **NEVER** extends it. Always use the earliest date. Do NOT use vaccine after the expiration date or beyond-use date.		
Thawing frozen vaccine	**Between:** ▪ 2°C and 8°C (36°F and 46°F) for 45 minutes. Let stand at room temperature (between 15°C and 25°C [59°F and 77°F]) for 15 minutes. OR ▪ 15°C and 25°C (59°F and 77°F) for 15 minutes		**Between:** ▪ 2°C and 8°C (36°F and 46°F) for 1 hour. Let stand at room temperature (between 15°C and 25°C [59°F and 77°F]) for 15 minutes. OR ▪ 15°C and 25°C (59°F and 77°F) for 45 minutes.

Transportation of Thawed Vials at 2°C to 8°C (36°F to 46°F)

- If transport at -50°C to -15°C (-58°F to 5°F) is not feasible, available data support transportation of one or more thawed vials for up to 12 hours at 2°C to 8°C (36°F to 46°F) when shipped using shipping containers which have been qualified to maintain 2°C to 8°C (36°F to 46°F) and under routine road and air transport conditions with shaking and vibration minimized
- Once thawed and transported at 2°C to 8°C (36°F to 46°F), vials should not be refrozen
- Thawed and transported vials should be stored at 2°C to 8°C (36°F to 46°F) until use

Additional Guidance: SPIKEVAX Package Insert | Moderna COVID-19 Vaccine (2023-2024 Formula) Fact Sheet | Moderna HCP Letter | https://eua.modernatx.com/

Vaccine Ordering and Distribution

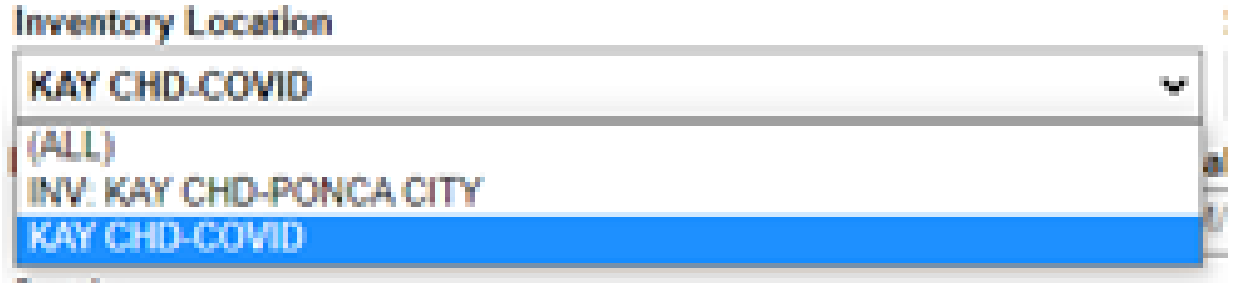
Teja Paruchuri, MPH

OKLAHOMA State Department of Health

Reconciliation

Reconciliation – every 14 days

- Providers are required to reconcile their inventory once every 14 days before placing a vaccine order.
- If a clinic does not reconcile COVID inventory every 14 days, they will not be able to create a vaccine order.
- An informational video on COVID 19 vaccine reconciliation and ordering can be accessed at https://vimeo.com/528424790
- Inventory Reconciliation



Ordering Process

- Providers can create orders in OSIIS during the ordering timeframe, which is **Tuesday through Monday**.
- COVID-19 vaccines are on allocation. Please do not order more vaccines than you can use in a 2-week period. Orders that have already been placed will be cut based on the availability of the vaccine and doses administered.
- Providers will no longer be able to order less than the minimum quantity for direct shipment.
  - The minimum order quantity is 10 doses for all formulations, except for Pfizer 6m-4yrs, which is 30 doses.

CVX	Name	NDC	Manufacturer Code	Manufacturer	Cost per Package	Doses per Package
CVX	NAME	NDC	MANUFA	MANUFA		
308	Pfizer-BT 2023-2024 (10 x 3 dose vials) 6m-4yrs	59267-4315-02	PFR	PFIZER, INC.		30
309	COMIRNATY 2023-2024 (10 x 0.3mL vials) 12+ yrs	00069-2362-10	PFR	PFIZER, INC.		10
310	Pfizer-BT 2023-2024 (10 x 0.3mL sdv vials) 5-11 yr	59267-4331-02	PFR	PFIZER, INC.		10
311	Moderna 2023-2024 (10 x 0.25mL sdv vials) 6m-11y	80777-0287-92	MOD	MODERNA		10
312	Spikevax 2023-2024 (10 x 0.5mL sdv vials) 12+ yrs	80777-0102-95	MOD	MODERNA		10

Ordering Process

- The cut-off to create orders in OSIIS – COB on Monday's.
- Orders that are submitted by Monday will be submitted to CDC for processing on Tuesdays and vaccine will be delivered by the end of the same week.
- To make any changes or cancellations to orders after the deadline, providers must reach out ASAP.
  - To request a change, a provider should email OSDH VaccineHelp <VaccineHelp@health.ok.gov>
  - If provider doesn't receive a confirmation of changes/cancellation within 24h, provider must call the OSDH Immunization Service 405.426.8580 to ensure that the order has been cancelled.
- Orders will directly be shipped to the providers. (subjected to change based on the available weekly threshold amounts).
- Please do not refuse any vaccine shipments.

Ordering Process

- Upon delivery of vaccine, providers should complete the following steps:
  1. Verify if the doses ordered and received are correct.
  2. Check if the delivered vaccines are viable. If the vaccines are not viable upon receipt or if there are doses missing, report it to Immunization Service on the same day.
  3. Immediately place vaccines into storage according to the storage guidelines.
  4. **Accept inventory in OSIIS.**
- Questions about orders:
  - OSIIS: OSIISHELP@health.ok.gov
  - Vaccine ordering process: VaccineHelp@health.ok.gov

Covid vaccine returns

Below is a summary of how to handle spoiled/expired/wasted COVID-19 vaccines.

COVID 19 vaccines received as part of the USG pandemic response

- These vaccines *cannot* be returned to McKesson.
- Once unauthorized, whether spoiled/expired/unused, these vaccines should be adjusted out of your inventory as wastage and properly disposed of according to state and local regulations.

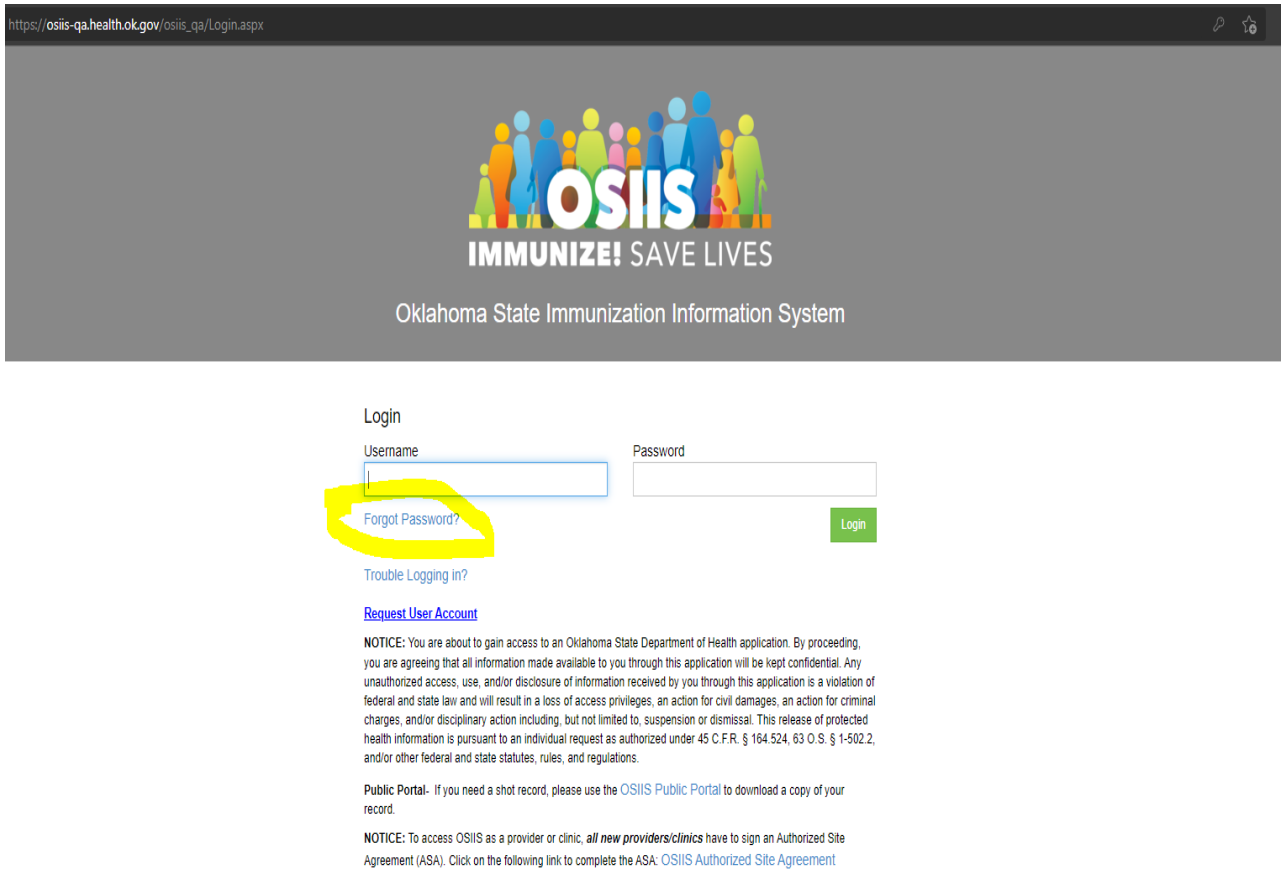
Updated 2023-24 COVID 19 vaccines received as part of CDCs routine program (VFC, 317, or Bridge Access Program)

- Spoiled or expired vaccines should be returned to Mckesson by creating vaccine returns in OSIIS just like any other routine vaccines.
- Any nonviable vaccines that cannot be returned to McKesson are considered wastage, including open multi-dose vials where not all doses have been administered, broken vials/syringes, vaccine drawn up into a syringe but not administered, etc. These vaccines should must be adjusted out of the inventory as wastage should be properly disposed of according to state and local regulations.

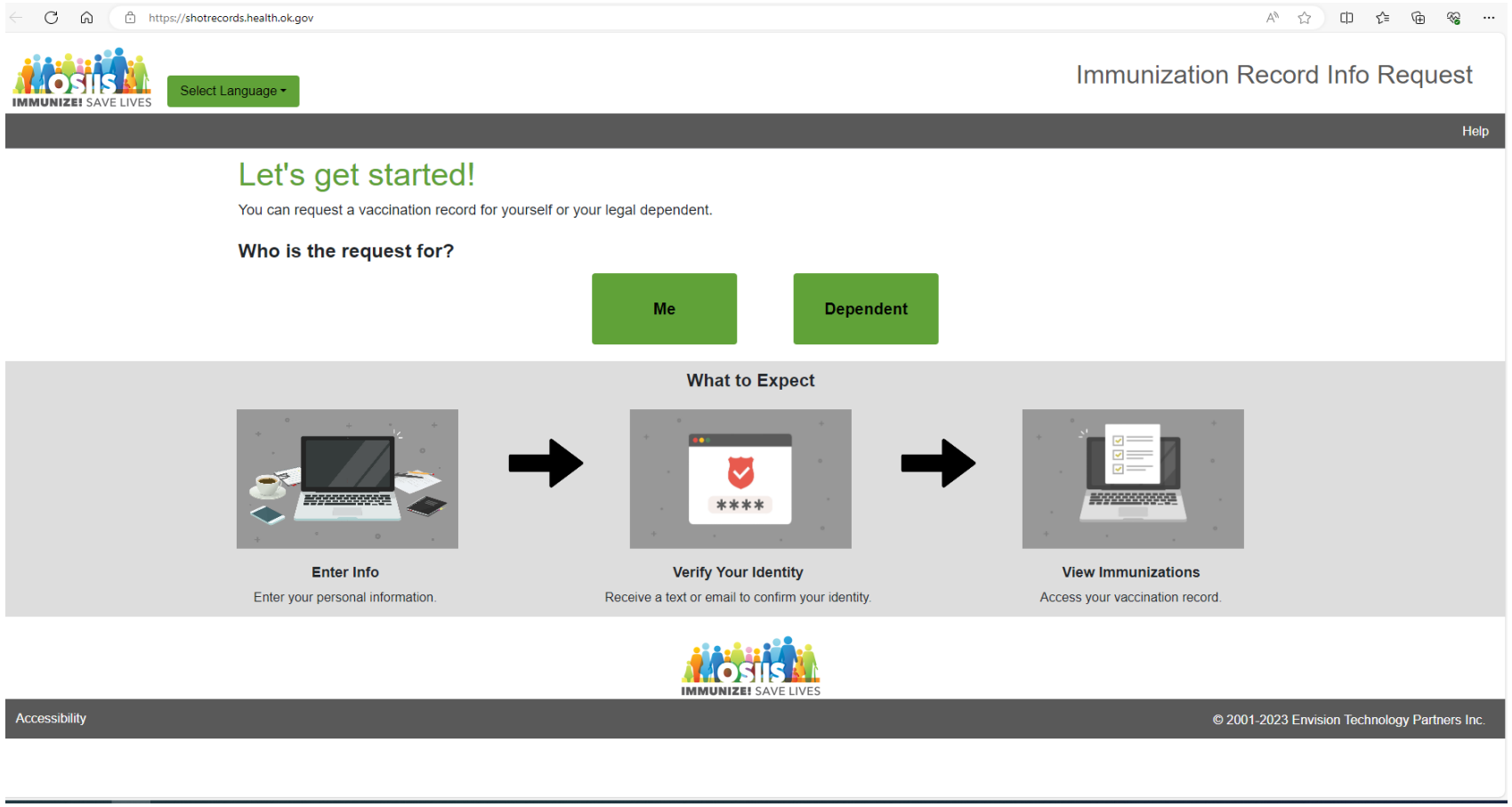
OSIIS Updates

Martin Lansdale, MPH
OSIIS Data Quality Coordinator

Updating Passwords in OSIIS



Public Portal: New Look!



Updated Public Portal

- OSIIS has a public portal that can be found at the below link and now is in English and Spanish!
  - https://shotrecords.health.ok.gov/
  - **DISCLAIMER:** Not all shots are recorded in OSIIS as reporting private vaccine is not required.

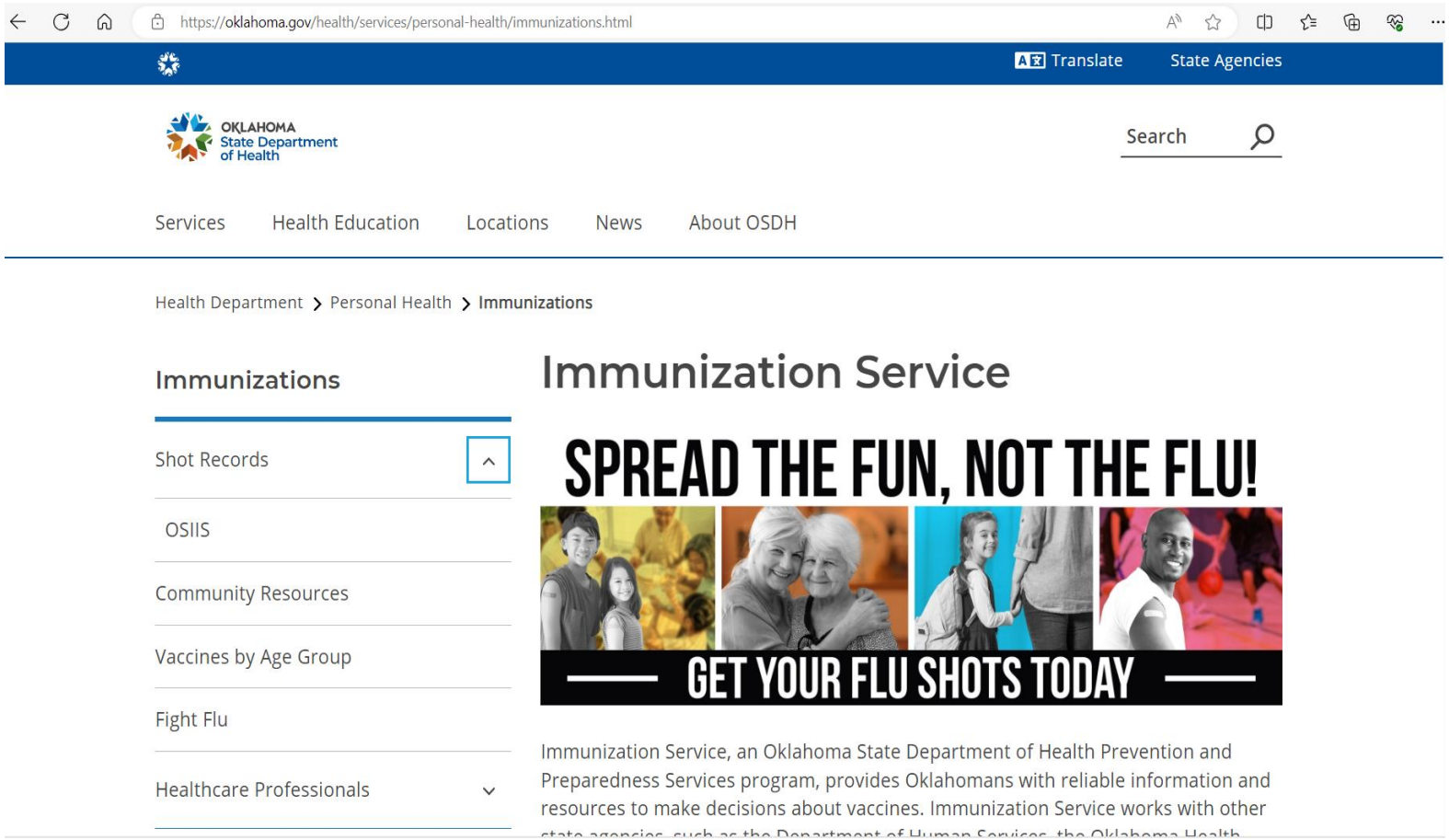
- Patients can search and download a copy of their shot record for just COVID shots or their complete immunization history through the portal.

- The public portal uses **patient name, date-of-birth, email, and phone number** for verification purposes (all have to be on the shot record in OSIIS or patients cannot pull their shot record).

- Currently OSIIS has a high amount of missing emails/phone numbers.

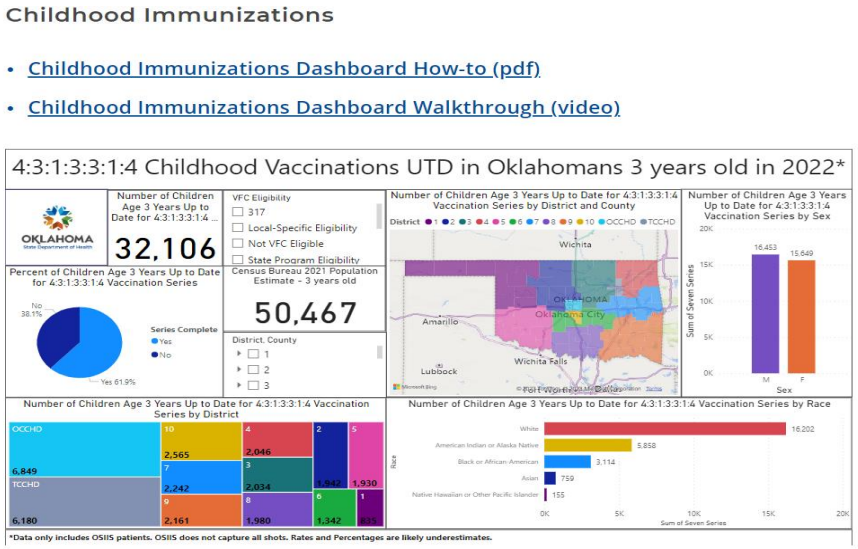
- Providers need to make sure to document email and phone number for the patient **and add/send it to OSIIS** with the shot record in order to increase the likelihood of a records match in the portal.

Immunization Services Website



Immunization Services Website

- The Immunization Services Website (Immunizations (oklahoma.gov) has been updated!
- Updated website includes a link for the public portal and includes VFC program information, community resources, OSIIS, helpful hints, FAQ's, and more.
- Site also now contains flu, covid, and Childhood Immunizations dashboards as well as links to Oklahoma immunization data, OSIIS data request's, tip sheets, and HL7 onboarding information.



How To Guides

"How To" Guides

- How to Turn On User Default Order Notifications
- Inventory Reconciliation
- How to Place a Covid-19 Vaccine Order
- Immunizing a Patient for COVID
- How to add an extra dose
- Wastage
- COVID-19 Vaccine Cleanup -Inventory Adjustment- Report Wastage OSIIS TipSheet.docx

Flu and RSV

Lauren Speer, BSN, RN.

Immunization and Communicable Disease Nurse Consultant, Nursing Services

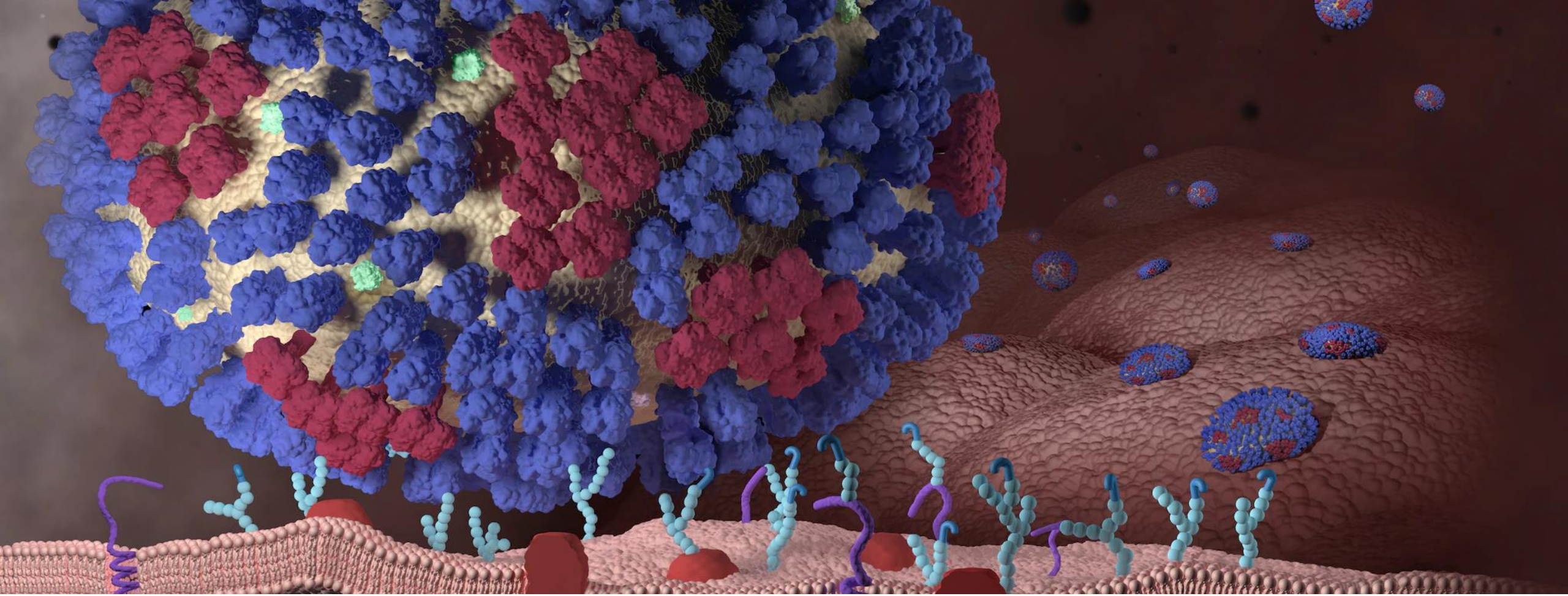
2023 – 2024

It’s Influenza Season

Let’s get ready to fight the flu!

Lauren Speer BSN, RN
Nursing Service
Immunization & Communicable
Disease Nurse Consultant

OKLAHOMA
State Department
of Health



Influenza

Influenza (also known as “flu”) is a contagious respiratory illness caused by influenza viruses. It can cause mild to severe illness, and at times can lead to death.

If you have asthma, diabetes, heart disease, or certain other chronic medical conditions, you're at risk for flu complications that can lead to hospitalization and even death. Vaccination is your best protection against flu.

Get the facts.
Get vaccinated.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

08233062-z

Take Action to Prevent Flu

- The best way to reduce your risk from seasonal flu and its potentially serious complications is to get vaccinated every year. Optimal time for flu vaccination is in October.

Everyday preventive actions to stop the spread of flu.

- Avoid close contact with people who are sick
- If you are sick, limit contact with others as much as possible to keep from infecting them.
- Cover coughs and sneezes.
- Cover your nose and mouth with a tissue when you cough or sneeze. Throw the tissue in the trash after you use it.
- Wash your hands often with soap and water. If soap and water are not available, use an alcohol-based hand rub.
- Avoid touching your eyes, nose, and mouth. Germs spread this way.
- Clean and disinfect surfaces and objects that may be contaminated with viruses that cause flu.
- For flu, CDC recommends that people stay home for at least 24 hours after their fever is gone except to get medical care or other necessities. Fever should be gone without the need to use a fever-reducing medicine.

IS IT A COLD OR FLU?

SIGNS AND SYMPTOMS	COLD	FLU
Symptom onset	Gradual	Abrupt
Fever	Rare	Usual
Aches	Slight	Usual
Chills	Uncommon	Fairly common
Fatigue, weakness	Sometimes	Usual
Sneezing	Common	Sometimes
Chest discomfort, cough	Mild to moderate	Common
Stuffy nose	Common	Sometimes
Sore throat	Common	Sometimes
Headache	Rare	Common

#FIGHT FLU

CDC

Influenza Vaccine

OKLAHOMA
State Department
of Health

How do flu vaccines work?

- Flu vaccines cause antibodies to develop in the body two weeks after vaccination.
- These antibodies provide protection against infection with circulating influenza viruses
- All flu vaccines in the US are quadrivalent vaccines that is they protect against four different flu viruses: Influenza A(H1N1) virus, Influenza A(H3N2)virus and two influenza B viruses

Quadrivalent Flu Vaccines

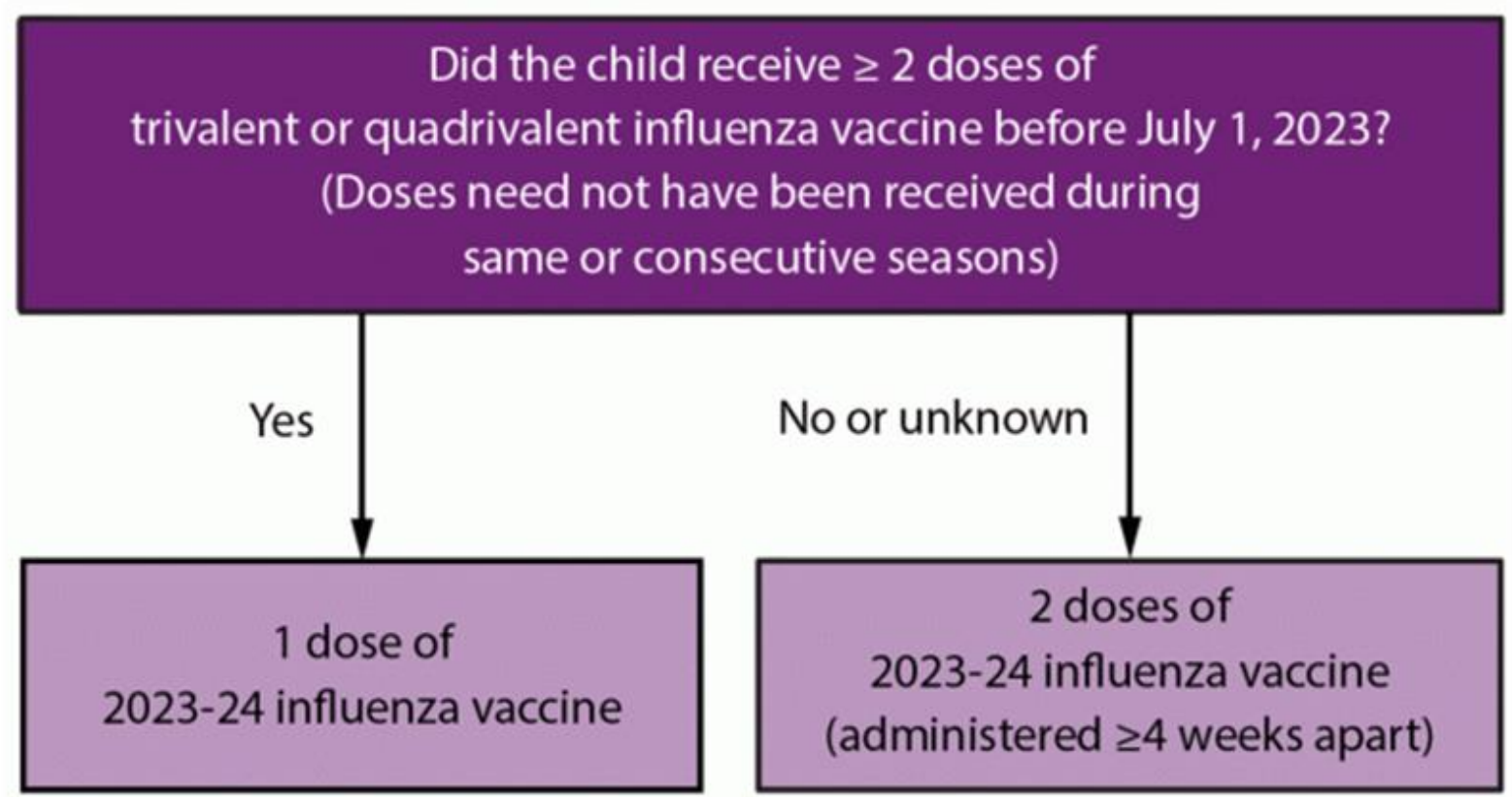
- Standard-dose unadjuvanted quadrivalent influenza shots that are manufactured using virus grown in eggs. These include Afluria Quadrivalent, Fluarix Quadrivalent, FluLaval Quadrivalent, and Fluzone Quadrivalent. Different influenza shots are licensed for different age groups. These four vaccines are approved for people 6 months of age and older. Most influenza shots are given in an arm muscle with a needle. One quadrivalent influenza shot (Afluria Quadrivalent) can be given either with a needle (for people aged 6 months and older) or with a jet injector (for people aged 18 through 64 years only).
- A quadrivalent cell-based influenza shot (Flucelvax Quadrivalent) containing virus grown in cell culture, which is licensed for people 6 months and older. This vaccine is egg-free.
- Recombinant quadrivalent influenza shot (Flublok Quadrivalent), an egg-free vaccine, approved for people 18 years and older.
- A quadrivalent flu shot using an adjuvant (an ingredient that helps create a stronger immune response), Fluad Quadrivalent, approved for people 65 years of age and older.
- A quadrivalent high-dose influenza vaccine Fluzone High-Dose, which contains a higher dose of antigen to help create a stronger immune response, licensed for people 65 years and older.
- A live attenuated influenza vaccine (FluMist Quadrivalent), which is given intranasally. This vaccine is approved for people 2 through 49 years of age. Live attenuated influenza vaccine should not be given to people who are pregnant, immunocompromised persons, and some other groups

- All people 6 months and older should get a flu vaccine which is age and health status appropriate

Influenza Vaccine Schedule

- 1 dose each influenza season for persons age 9 years or older
- For children aged 6 months through 8 years, the number of doses of influenza vaccine needed for the 2023–24 influenza season is determined as follows:
  - Those who have previously received ≥2 total doses of trivalent or quadrivalent influenza vaccine ≥4 weeks apart before July 1, 2023, require only 1 dose for the 2023–24 season. The previous 2 doses of influenza vaccine do not need to have been received in the same season or consecutive seasons.
  - Those who have not previously received ≥2 doses of trivalent or quadrivalent influenza vaccine ≥4 weeks apart before July 1, 2023, or whose previous influenza vaccination history is unknown, require 2 doses for the 2023–24 season. The interval between the 2 doses should be ≥4 weeks.

Influenza Vaccine Schedule



Who Should Not Be Vaccinated

Flu Shots:

- Children younger than 6 months of age are too young to get a flu shot.
- People with severe, life-threatening allergies to any ingredient in a flu vaccine (other than egg proteins) should not get that vaccine. This might include gelatin, antibiotics, or other ingredients.
- People who have had a severe allergic reaction to a dose of influenza vaccine

Nasal Spray Flu Vaccine:

- Children younger than 2 years of age.
- Adults 50 years of age and older.
- People who have had a severe or life-threatening allergic reaction to any ingredient in the nasal spray vaccine (other than egg proteins).
- People who have had a severe allergic reaction to any flu vaccine.
- Children and adolescents 2 through 17 years of age who are receiving aspirin- or salicylate-containing medications.
- People with weakened immune systems (immunosuppression) due to any cause, including (but not limited to) immunosuppression from medications, congenital or acquired immune disorders, HIV infection, or asplenia.
- People who care for or are close contacts of severely immunocompromised persons who require a protected environment (or otherwise avoid contact with those persons for 7 days after getting the nasal spray vaccine).
- Pregnant people.
- Children 2 years through 4 years who have asthma or who have had a history of wheezing in the past 12 months.
- People with cerebrospinal fluid (CSF) leaks (communication and leakage of fluid between the space surrounding the brain and the nose, throat, ear, or any other place in the head).
- People with cochlear implants.
- People who have recently taken influenza antiviral drugs. This depends on the specific influenza antiviral medication that was taken, and how recently the last dose was taken.

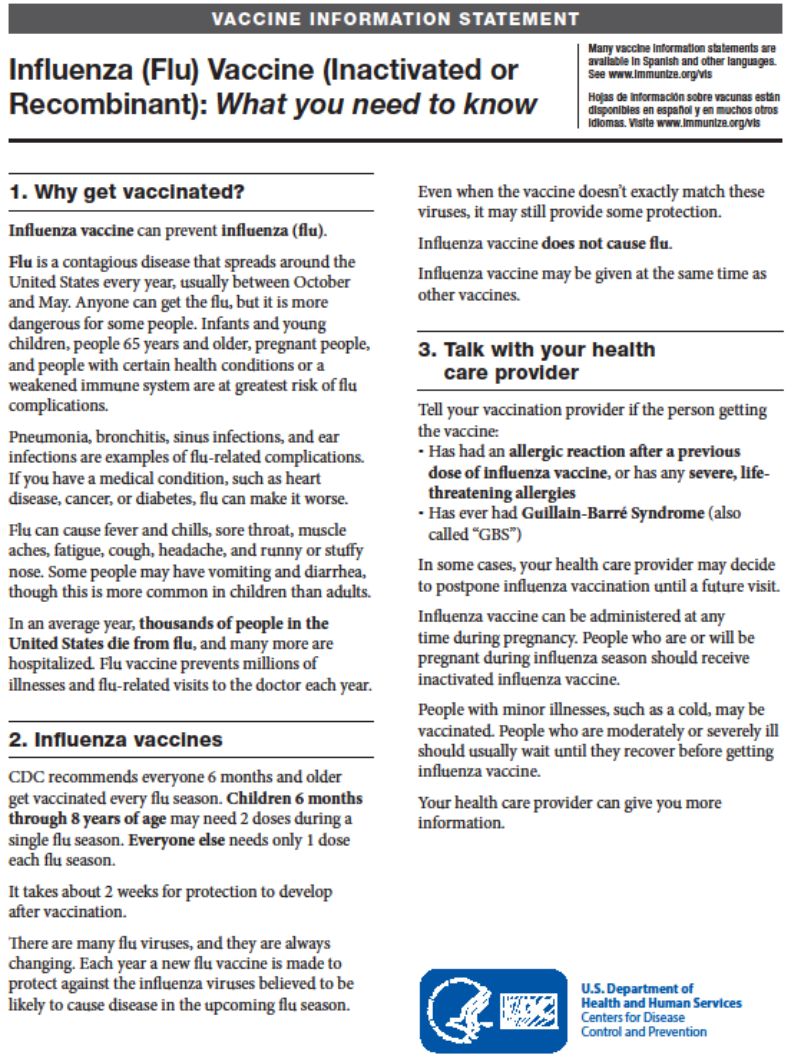
Vaccine Information Statement

- **Provide a Vaccine Information Statement (VIS) when a vaccination is given.**

1. to the parent or legal representative[1] of any child to whom the provider intends to administer such vaccine, or
2. to any adult[2] to whom the provider intends to administer such vaccine.

- **Record information for each VIS provided.**

1. the edition date of the VIS distributed, and
2. the date the VIS was provided.
3. the name, address and title of the individual who administers the vaccine,
4. the date of administration, and
5. the vaccine manufacturer and lot number of the vaccine used.



VACCINE INFORMATION STATEMENT

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 and older, pregnant people, 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.

In an average 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 vaccines

CDC recommends everyone 6 months 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 the influenza viruses believed to be 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 vaccination 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 until a future visit.

Influenza vaccine can be administered at any time during pregnancy. People who are or will be pregnant during influenza season should receive inactivated influenza vaccine.

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.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Can you get the flu from the flu shot?

- No

The flu vaccine is inactivated and it usually takes about 2 weeks to build antibodies to help prevent the flu.

Respiratory Syncytial Virus (RSV)

OKLAHOMA State Department of Health

RSV for infants and young children

- RSV activity in the United States usually begins October 1 and concludes March 31; although there can be regional variation.
- Two monoclonal antibody products – nirsevimab (Beyfortus) and palivizumab (Synagis) – can help protect babies and young children from severe disease from an RSV infection. Monoclonal antibodies are not vaccines. They provide an extra layer of defense that helps fight RSV infections and protect children from getting very sick. The protection these antibodies provide wanes over time. These products are not treatments for a child who already has RSV infection.
- Can be co-administered with other immunizations.

BEYFORTUS (nirsevimab-alip)

- 1 dose of Nirsevimab of all infants younger than 8 months born during or entering their first RSV season.
- 1 dose of Nirsevimab for infant and children 8-19 months old who are at increased risk for severe RSV disease and entering their second season.
- Dosing:
  - ❖ Less than 5 kg recommended dose is 50 mg
  - ❖ 5 kg and greater recommended dose is 100 mg
- Nirsevimab will come in a prefilled syringe.

Store refrigerated between 36°F to 46°F (2°C to 8°C).
BEYFORTUS may be kept at room temperature 68°F to 77°F (20°C to 25°C) for a maximum of 8 hours.
After removal from the refrigerator, BEYFORTUS must be used within 8 hours or discarded.
Do not freeze. Do not shake.

RSV for infants and young children

Synagis (palivizumab)

- Palivizumab is limited to children under 24 months of age with certain conditions that place them at high risk for severe RSV disease. It must be given once a month during RSV season.
- Palivizumab is administered at a dosage of 15mg/kg.
- Prefilled syringe: 50mg/0.5 mL or 100mg/1.0 mL

Upon receipt and until reconstitution for use, Synagis® (palivizumab) should be stored between 2 and 8°C (35.6° and 46.4°F) in its original container. Do not freeze. Do not use beyond the expiration date.

- Preparation for Administration
  - ❖ To reconstitute, remove the tab portion of the vial cap and clean the rubber stopper with alcohol pad.
  - ❖ Both vials contain an overfill to allow the withdrawal when reconstituted.
  - ❖ Slowly add 0.6 mL of sterile water for injection to the 50 mg vial or add 1.0 mL of sterile water for injection to the 100 mg vial.
  - ❖ The vial should gently be swirled for 30 seconds to avoid foaming. Do Not Shake.
  - ❖ Reconstituted Synagis® (palivizumab) should stand at room temperature for a minimum of 20 minutes until the solution clarifies.
  - ❖ Reconstituted Synagis® (palivizumab) does not contain a preservative and should be administered within 6 hours of reconstitution.

RSV Vaccine in Adults 60 and older

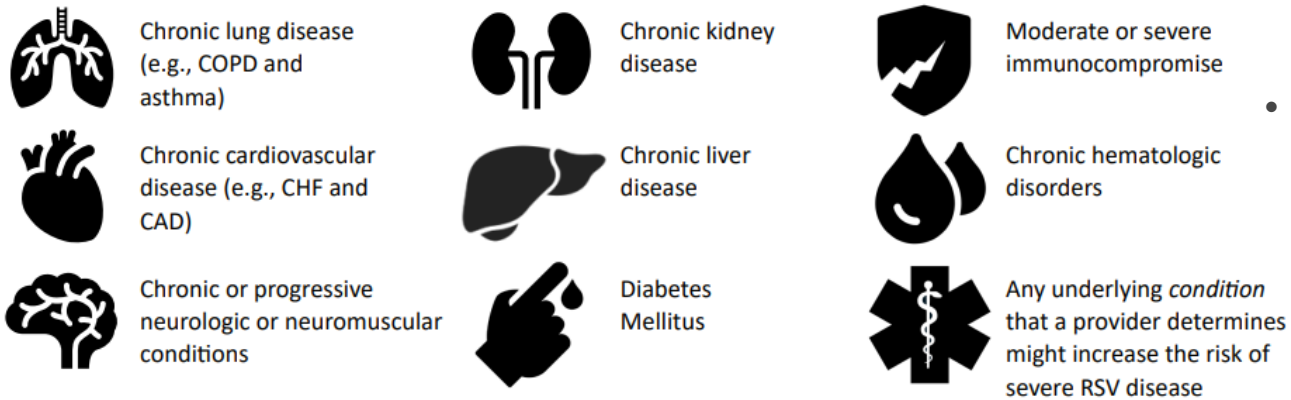
- Each year in the United States, RSV leads to approximately 60,000-160,000 hospitalizations and 6,000-10,000 deaths among adults 65 years and older.
- There are two RSV vaccines approved for adults 60 and older
  - ❑ Arexvy (RVCPreF3)
  - ❑ Abrysvo (RSVpreF)
- Both vaccines contain a part of the RSV virus by causing an immune response that can protect you from respiratory disease if someone is infected with RSV in the future.
- Clinicians should discuss RSV vaccination with adults ages 60 years and older.
- When should someone get the RSV Vaccine?
  - ❑ For the 2023-2024 season, 60 and older with shared clinical decision making with your health care provider (anyone who provides or administers vaccines, including primary care physicians, specialists, physician assistants, nurse practitioners, registered nurses, and pharmacists) can assist the client with the decision to get the vaccine.
- For other points to consider review the screening checklist for contraindications to vaccine to ensure there are no contraindications to receiving the vaccine. (e.g. severe allergic reaction to any component of the vaccine or serious neurological conditions, including Guillain-Barre Syndrome (GBS)

RSV Vaccine in Adults 60 and Older

Shared Clinical Decision Making-

- Adults ages 60 years and older who are most likely to benefit, including those with certain chronic medical conditions associated with increased risk of severe RSV disease.

Underlying medical conditions associated with increased risk for severe RSV disease include:



- Adults with advanced age and those living in nursing homes or other long-term care facilities are also at increased risk of severe RSV disease and may benefit from RSV vaccination.
- Healthcare providers should also talk to their patients about other vaccines (e.g., COVID-19, influenza) available this fall to help prevent respiratory illness.
- Healthcare providers can co-administer the vaccines for which a patient is eligible in the same visit, including RSV, COVID-19, and influenza vaccines.

AREXVY (GSK adjuvanted RSV vaccine)

- Administer a single dose of 0.5 mL intramuscularly.
- Will require reconstitution:

Figure 1. Cleanse both vial stoppers. Using a sterile needle and sterile syringe, withdraw the entire contents of the vial containing the adjuvant suspension component (liquid) by slightly tilting the vial. Vial 1 of 2.

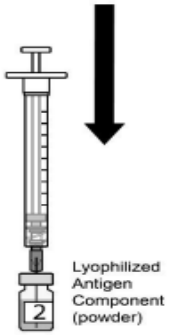


Figure 2. Slowly transfer entire contents of syringe into the lyophilized antigen component vial (powder). Vial 2 of 2.

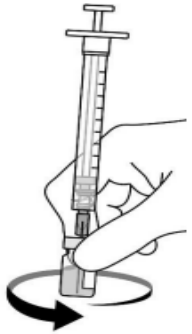


Figure 3. Gently swirl the vial until powder is completely dissolved. **Do not shake vigorously.**

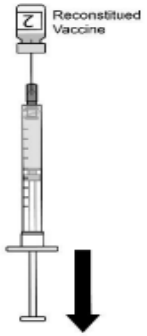
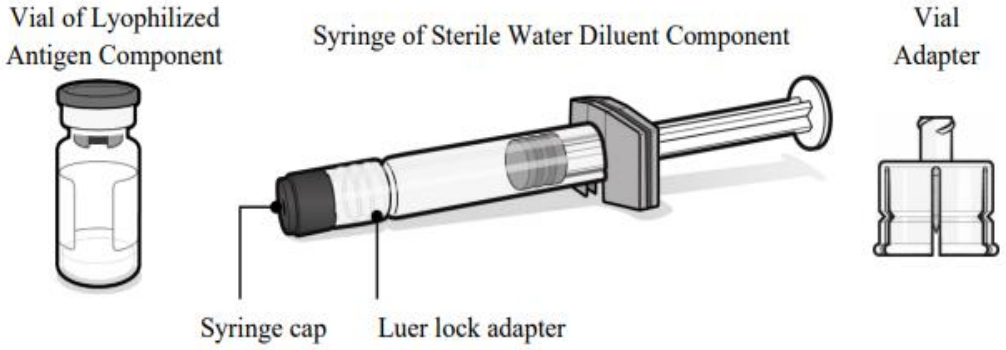


Figure 4. After reconstitution, withdraw 0.5 mL from the vial containing the reconstituted vaccine and administer intramuscularly.

- Store refrigerated between 2°C and 8°C (36°F and 46°F). Do not freeze. Discard if the antigen component has been frozen.
- After reconstitution, administer AREXVY **immediately** or store protected from light in the refrigerator between 2°C and 8°C (36°F to 46°F) or at room temperature up to 25°C (77°F) and use within 4 hours. Discard reconstituted vaccine if not used within 4 hours.
- Commonly reported side effects are pain at the injection site, fatigue, myalgia, headache, and arthralgia.

RSV Vaccine for Pregnant Women- ABRYSVO (Pfizer RSV vaccine)

- ABRYSVO (used for Adults 60+ as well) is a vaccine indicated for active immunization of pregnant individuals at 32 through 36 weeks gestational age for the prevention of lower respiratory tract disease (LRTD) and severe LRTD caused by RSV in infants from birth through 6 months of age.
- Administered intramuscularly 0.5 mL prefilled syringe
- ABRYSVO will need to be reconstituted



- Store in refrigerator at 2°C to 8°C (36°F to 46°F) in the original carton. Do not freeze.
- After reconstitution, administer **immediately** or store at room temperature 15°C to 30°C (59°F to 86°F) and use within 4 hours. Discard reconstituted vaccine if not used within 4 hours.
- Commonly reported side effects are pain at the injection site, headache, muscle pain, and nausea in pregnant women.
- Commonly reported side effects are fatigue, headache, pain at the injection site, and muscle pain for adults 60+.

Thank you!

Questions?

Thank you!

OKLAHOMA
State Department
of Health

Questions/Suggestions

Looking Forward:
Next Call
January 5th, 2024
at 12pm

OKLAHOMA State Department of Health

Resources: Medical Updates & Immunization Site Training for All Healthcare Providers led by Pfizer Vaccines US Medical Affairs

Goal: Educate providers and immunization staff personnel on the proper use of the Pfizer-BioNTech COVID-19 Vaccines

To access dates and links for upcoming training sessions, please visit*:

https://www.pfizermedicalinformation.com/en-us/medical-updates

Resources

Testing:

- Nasopharyngeal, throat, saliva
- Testing@health.ok.gov

Monoclonal Antibodies: (Amanda Cavner)

- Antivirals@health.ok.gov
- https://oklahoma.gov/covid19/what-you-should-know/monoclonal-antibody-therapies.html

Vaccine:

- COVID-19 Vaccines | FDA
- PREP Act Guidance
- Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC
- COVID-19 Vaccination for Children | CDC
- Pfizer: Home (cvdvaccine-us.com)
- Moderna: What is Moderna COVID-19 Vaccine (EUA)? | How Does It Work? (modernatx.com)
- Novavax: https://us.novavaxcovidvaccine.com/hcp

Resources/Tools

- OSIIS Training: https://osiis.health.ok.gov/osiis/Application/ApplicationHelp/Index

Vaccine Inventory Adjustment: On-Hand Expired Vaccines

- **When reconciling inventory, check that your facility has no expired inventory on hand.**
  - Navigate to the *Vaccine Inventory On-Hand* screen by selecting:
    - **Inventory** > **Vaccines** > **On-Hand** from the left-hand menu.
- Change the Status from On-Hand to Depleted/Expired
- Locate the Filter tab
- Locate the vaccine inventory item requiring an inventory adjustment.
- Click the corresponding **Action** button and select **Adjustment**.
- Complete the following required fields:
  - **Date** (enter the actual date on which the inventory was wasted)
  - **Reason** (select Vtrcks Other)
  - **Modification** (if a value does not default, select Add or Subtract to make the corresponding adjustment)
  - **Doses Adjusted** (enter the number of doses wasted for the selected reason)
  - **Comments** (Expired)
- Click the **Create** button.
- Click the **On-Hand** menu item to return to the *Vaccine Inventory On-Hand* screen where you can verify the inventory was adjusted correctly.
- **See attached video on Resources/Tools**

QAs From Live Call