Vaccine Summit

September 21, 2023: Elgin

Illinois Department of Public Health
IDPH
Protecting Health, Improving Lives

Illinois Chapter
INCORPORATED IN ILLINOIS
American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

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SESSION 1:
IDPH VFC PROGRAM

Monica Del Ciello

- MPH
- Senior Program Manager
- Ball State, UIC

Learning Objectives:

After this session participants will be able to

1

Use the Illinois Comprehensive Automated Immunization Registry Exchange (I-CARE) portal to order and maintain vaccines.

2

Describe inventory reconciliation best practices for I-CARE and VFC I-CARE mandates.

3

Implement effective vaccine storage and handling practices and keep vaccine waste to a minimum.

Overview of the VFC Program

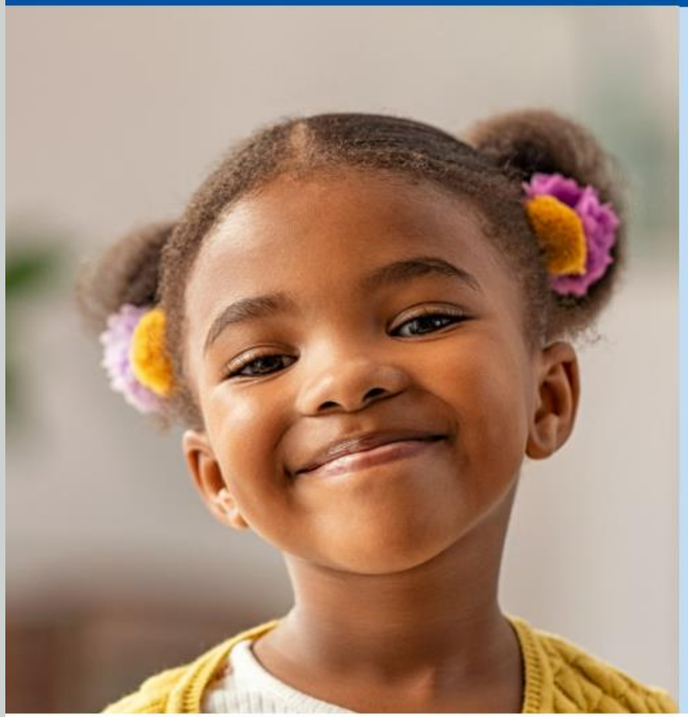
- IL's VFC program is federally-funded by the Centers for Disease Control and Prevention (CDC).
- Provides vaccines at no cost to children who may not otherwise get them due to cost.
  - Children who are eligible to receive VFC vaccines need to be 18 years and younger and one of the following:
    - Uninsured or Underinsured
    - Medicaid Title 19 or 21 eligible.
    - American Indian or Alaskan Native.
- Children who are **underinsured** can access VFC vaccines at federally qualified health centers (FQHCs), rural health clinics, and some local health departments that are deputized by FQHCs or RHCs.

Benefits

Vaccines for Children

Protecting America's children every day

The Vaccines for Children (VFC) program helps ensure that all children have a better chance of getting their recommended vaccines. VFC has helped prevent disease and save lives.



CDC estimates that vaccination of children born between 1994 and 2021 will:

prevent **472 million** illnesses
(29.8 million hospitalizations)

more than the current population of the entire U.S.A.

help avoid **1,052,000** deaths

greater than the population of Seattle, WA

save nearly **$2.2 trillion** in total societal costs
(that includes $479 billion in direct costs)

more than $5,000 for each American

Updated 2021 analysis using methods from "Benefits from Immunization during the Vaccines for Children Program Era—United States, 1994-2021."

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

www.cdc.gov/vaccines/vfcprogram/

NCIRDWTLC | 10/28/22

VFC Provider Requirements

VFC providers must:

- ✓ Be licensed in Illinois to administer vaccines to children aged 18 and younger.
- ✓ Be willing and able to follow all VFC program requirements, policies, and procedures, including participation in site visits and educational opportunities.
- ✓ Have capacity to order, receive, manage, store, and monitor the temperature of public vaccines.
- ✓ Be open at least four consecutive hours for three days a week to receive VFC vaccines.

I-CARE

- The I-CARE Registry is an electronic web-based immunization data registry operated by the Illinois Department of Public Health (IDPH) as authorized by the Immunization Data Registry Act, 410 ILCS 527.
- All VFC providers must be enrolled in I-CARE.
  - Enrollment and vaccine management is completed in I-CARE.
- Must be able to provide individual patient immunization records on how each VFC vaccine was administered.
- Patient immunization records can be entered manually or electronically through the provider's electronic medical record.

Submitting and Exchanging Data

- Share Electronic Health Record (EHR) with I-CARE using HL7 data exchange.
  - Contact EHR vendor to determine if your system is HL7 compatible.
  - May need to acquire an additional interface for your EHR to send and exchange immunization data.

For more information on HL7 please visit IDPH's I-CARE site. If you have questions, please contact dph.icare@illinois.gov.

Provider Profile

- Providers must submit a Provider Population Profile at initial program enrollment and at least annually or when order patterns indicate a change.
- All VFC programs must determine individual provider populations served and associated vaccine need by fund type.
- This ensures publicly purchased vaccines are distributed in amounts representing the provider population served and to adjust as populations change.

Record Keeping

VFC providers must comply with:

- Distributing the most current vaccine information statements (VISs) for all vaccines included in National Childhood Vaccine Injury Act (NCVIA).
  - Immunize.org: Vaccine Information Statements (available in 47 languages)
- Reporting adverse reactions to VAERS.

Table 1. Guidance for Use of Vaccine Information Statements
(Source: AAP Committee on Medical Liability. Medical Liability for Pediatricians, 6th Edition. 2004)

Distribution	Documentation in the Patient's Medical Record
Must be provided each time a National Vaccine Injury Compensation Program (VICP)-covered vaccine is administered*	Vaccine manufacturer, lot number, and date of administration*
Given to parent, legal guardian, or patient (non-minor) to keep*	Name and business address of the physician administering the vaccine*
Must be the current version†	Vaccine Information Statement version date and date it is provided†
Can provide (not substitute) other written or audio-visual materials as necessary‡	Site (eg, deltoid area), route of administration (eg, intramuscular), and expiration date of the vaccine‡

*Required under the National Childhood Vaccine Injury Act.
†Required under Centers for Disease Control and Prevention instructions implementing the National Childhood Vaccine Injury Act.
‡Recommended by the American Academy of Pediatrics.

Record Keeping

The National Childhood Vaccine Injury Act (NCVIA) and/or CDC requires physicians to document the:

- Name of vaccine administered
- Date of vaccine administration
- Vaccine manufacturer
- Vaccine lot number
- Name, title, and business address of the healthcare professional who administered the vaccine
- Date the VIS was provided to the parent/guardian and VIS version date

The AAP recommends also recording the:

- Site and route of administration
- Vaccine expiration date
- Statement indicating that the VIS was provided and discussed with the parent
- Any vaccine under CDC contract requires a VIS.

The CDC requires that patient VFC eligibility screening must take place with each immunization visit.

Maintain records for a minimum of three years or longer, if required by state law (even in the case of provider retirement or provider location closure).

Required Documentation

- Providers must complete CDC's Provider Agreement.
- The medical director in a group practice must be authorized to administer pediatric vaccines under state law.
- The provider signing the Provider Agreement on behalf of a multi-provider practice must have authority to sign on behalf of the entity.
- All licensed providers in an enrolled practice must be listed with professional license numbers and individual NPI numbers (VFC Enrollment Form).

Recertification of Annual Enrollment

- Provider agreement forms (signed by medical director or equivalent in a group practice*).
- The practitioner will be held accountable for compliance by the entire organization and its VFC providers with the responsible conditions outlined in the Provider Enrollment Agreement.

Recertification of Annual Enrollment

All VFC providers must recertify their enrollment annually to continue participating in the VFC program.

- Annual enrollment is submitted in I-CARE.

Additionally, providers should:

- Review and Agree to the VFC Eligibility and the VFC Loss and Replacement Policies.
- Review, sign, and upload the VFC Provider Agreement.

Provider Unenrollment

- Either the Provider or the Illinois VFC program may decide to terminate the provider agreement at any time.

- Providers who wish to terminate the provider agreement must:
  - Complete unenrollment form.
  - Stop using VFC vaccines as of the withdrawal date.
  - Return any unused VFC vaccines back within 30 days.

- Examples of why IDPH may terminate the provider agreement include:
  - Provider has not ordered vaccine in the past 12 months.
  - A provider is on the List of Excluded Individual and Entities (LEIE) list maintained by Office of the Inspector General.
  - Failure to comply with requirements.

Vaccine Staff and Training – Vaccine Coordinators

Identify: a primary vaccine coordinator and at least one backup vaccine coordinator for each facility.

The primary and backup vaccine coordinators:

- Responsible for ordering, receiving, rotating, and monitoring vaccines.
- Responsible for ensuring all vaccines are stored and handled correctly.
- Must be fully trained on routine and emergency SOPs for vaccine ordering, storage, handling, transport, and inventory management.

More information about coordinator responsibilities can be found in the Vaccine for Children Program Manual for Illinois VFC Providers.

Notify IDPH when there is a change in vaccine coordinators or medical director.

Education Requirements

- Annual vaccine storage and handling training.
  - Documentation of training must be retained and submitted with annual enrollment (reviewed during site visits).

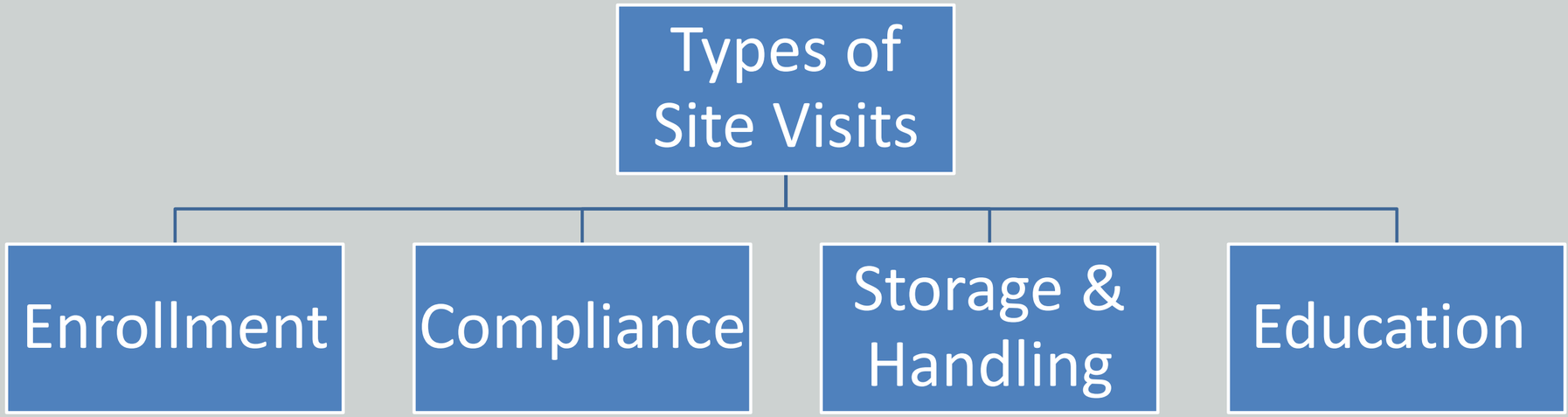
- Education is available through:
  - Some VFC site visits.
  - This summit ☺
  - CDC online training with **both** of the following modules:
    - You Call The Shots – Module 10 – Storage and Handling
    - You Call the Shots – Module 16 – Vaccines for Children Program

Staff Training

- All staff members who:
  - Receive vaccine deliveries
  - Handle or administer vaccines

  should be trained in vaccine-related practices and storage and handling SOPs.
- Training must be documented on the vaccine management plan.

VFC Site-Visits



VFC Enrollment Visits

- All providers (newly enrolling or re-enrolling after an absence) must have an enrollment site visit **before** being approved to order VFC vaccines.
- The purpose of this visit is to:
  - Educate providers about VFC program requirements.
  - Educate providers on proper vaccine storage and handling.
  - Certify providers have the appropriate resources to implement requirements.
- Providers should be prepared for follow-up visits during the first year.

VFC Compliance Visits

- VFC providers agree to program site visits that will determine compliance with requirements.
- A new provider must be enrolled and active in the VFC program for 3-6 months before a receiving a compliance site visit.
- Compliance visit includes review of and ensuring compliance with:
  - Provider Profile.
  - Vaccine ordering and inventory management.
  - Policies and procedures and vaccine management plan.
  - Vaccine storage and handling equipment, procedures, and documentation.
  - VFC screening requirements and billing practices.
  - All ACIP vaccines are available to VFC-eligible patients.
  - VFC-related document retention.

VFC Storage & Handling Visits

- Storage and Handling visits may be announced (scheduled) or unannounced.

- IDPH is required to complete unannounced storage and handling site visits for a percentage of providers each year.

- Compliance visit includes review of and ensuring compliance with:
  - Vaccine inventory management.
  - Vaccine storage and handling equipment and monitoring.
  - Vaccine storage and handling procedures and Vaccine management plan.
  - Appropriate storage and handling related documentation.

Vaccine Replacement

- VFC providers agree to replace vaccines purchased with state and federal funds that are deemed non-viable due to provider negligence on a dose-for-dose basis with privately purchased vaccines.

Fraud and Abuse

- By enrolling in the VFC program, you agree to comply with all program requirements

  Examples of fraud and abuse:
  - Providing VFC vaccines to non-VFC eligible children.
  - Billing a patient or third party for a VFC vaccine.
  - Denying VFC eligible children a VFC vaccine due to inability to pay an administration fee.
  - Failing to screen for and document eligibility at each visit.
  - Failing to properly maintain VFC records and requirements.
  - Failing to properly store and handle VFC vaccines, etc.

- The Department will investigate to determine intentional or unintentional fraud/misuse
  - If intentional, further investigation is necessary.

Patient Eligibility Screening and Documentation*

- Providers must screen, document, and verify VFC eligibility with every vaccine visit **before** administering vaccines.
- Use the MEDI system or equivalent system (with HFS 270/271 electronic transaction data).
- The Patient Eligibility Screening Form provides a means of recording responses to VFC eligibility questions.
  - The provider, parent, or guardian may complete the VFC eligibility portion of the form.
  - Verification of parent/guardian responses is not required.

Memorandum of Understanding (MOU) with FQHC or Rural Health Center

- Underinsured VFC-eligible children can only receive VFC vaccine from a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC).
- A local health department (LHD) can be **deputized** by an FQHC or RHC to allow the LHD to vaccinate underinsured VFC-eligible children.
- A Memorandum of Understanding (MOU) form is available through IDPH. It must be signed by three parties: the LHD, the FQHC or RHC, and IDPH.
- If a provider is not a FQHC, RHC or a deputized local health department, they should refer underinsured VFC-eligible children to a qualified provider location.

Important Announcements from IDPH Sent to VFC Providers on 9/6/2023

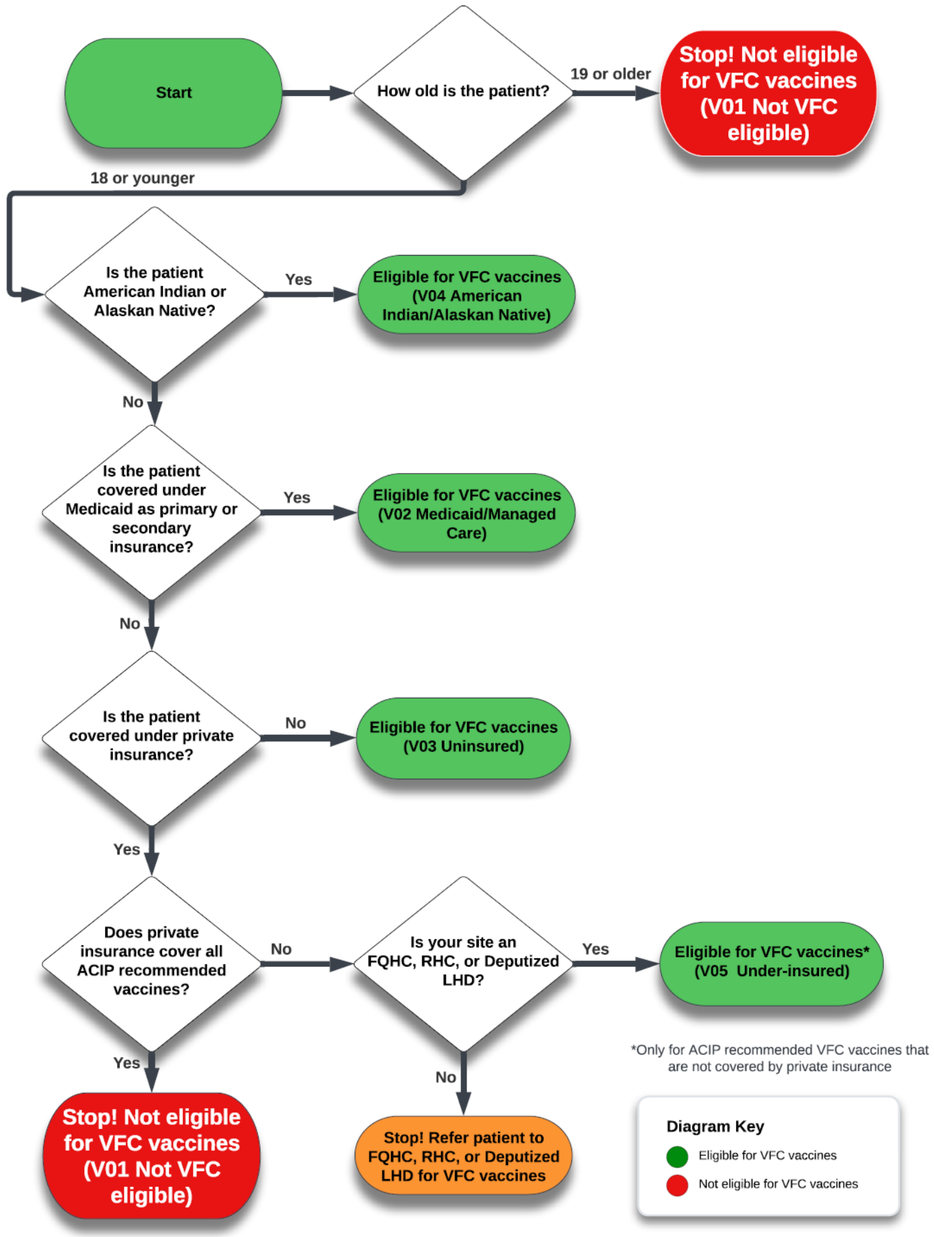
- Because of Medicaid Expansion, all Medicaid-enrolled children 18 years of age or younger are now VFC-eligible regardless of their Title 19, Title 21, or State-Funded Medicaid Status.

- How this impacts providers:
  - Medi should be checked at each encounter to ensure the patient is enrolled in Medicaid, but providers no longer need to check for Title 19, Title 21, or State Funded status.
  - When marking the patient VFC eligibility in your patient's chart and in I-CARE, the V02 Medicaid/Medicaid Manage Care status should be selected for all **Medicaid-enrolled children.**

VFC Eligibility Status Code Information and Associated Inventory Deductions		
VFC Eligibility Status Code	**VFC Code will deduct from this Inventory in I-CARE**	**Comments**
V00: Eligibility not determined/unknown	Private	Do not use for public vaccine programs.
V01: Not VFC eligible	Private	Do not use for public vaccine programs.
V02: Medicaid/Medicaid Managed Care	VFC	Use for all Medicaid-enrolled children through 18 years of age.
V03: Eligible-Uninsured	VFC	
V04: Eligible-American Indian/Alaska Native	VFC	
V05: Eligible-Federally Qualified Health Center patient (under-insured)	VFC	
V07: Local program eligibility	Private	Not currently used by Illinois or Chicago VFC.
V22: CHIP	VFC	This status is no longer applicable to Illinois or Chicago VFC patients. It will continue to deduct from VFC while providers transition to this new process, but providers should stop using this code. Use "V02: Medicaid/Medicaid Managed Care" instead.
V23: 317	317	
V24: Medicare	Private	Not currently used by Illinois or Chicago VFC.
V25: State program eligibility	Private	Not currently used by Illinois or Chicago VFC.

VFC ELIGIBILITY DECISION TREE

Effective 09/06/2023



Eligibility

VFC Eligibility Criteria	Definition
American Indian or Alaska Native (AI/AN)	This population is defined by the Indian Health Care Improvement Act (25 U.S.C. 1603). (AI/AN children are VFC-eligible under any circumstance.)
Medicaid-eligible	Children who are eligible for the Medicaid program. For the purposes of the VFC program, the terms “Medicaid-eligible” and “Medicaid enrolled” are used interchangeably.
Uninsured	Children not covered by any health insurance plan.
Underinsured	Underinsured means the child has health insurance, but the insurance policy: • Does not include any vaccines; • Does not include all vaccines recommended by the Advisory Committee on Immunization Practices (ACIP); or • Has a fixed dollar limit or cap for vaccines. Underinsured children are only eligible to receive VFC vaccines at a FQHC, RHC, or a deputized provider.

Eligibility – American Indian or Alaska Native (AI/AN)

- AI/AN children are VFC-eligible under any circumstance.
  - Participation is voluntary.
- When an AI/AN child also fits a second VFC eligibility category, the provider should always choose the category that will cost less for the family.
  - Depending on the facility, when an AI/AN parent chooses to have their child vaccinated, the parent may be responsible for the vaccine administration fees if the vaccines are delivered through the VFC program.
  - If the child has private insurance, it may result in fewer out-of-pocket costs for the child to receive privately purchased vaccinations since the insurance would likely cover the vaccine without cost-sharing.
  - If the AI/AN child is also Medicaid eligible, Medicaid should be used for the administration fee because it will provide the least out of pocket expense.

Eligibility – Insured Children with Medicaid

- Some children may have a private primary health insurance plan with Medicaid as their secondary insurance.
  - These children are considered VFC-eligible because of their Medicaid enrollment.
  - Their parents are not required to participate in the VFC program.

- There are billing options and the provider should choose the option that is most cost-effective for the family.
  - The parent of a child with Medicaid as secondary insurance should **never** be billed for a vaccine or an administration fee.

Eligibility – Insured Children with Medicaid

Option 1: The provider can administer VFC vaccines and bill Medicaid for the administration fee.

Considerations:

- Easiest way for a provider to use VFC vaccines and bill Medicaid for the administration fee.
- No out-of-pocket costs to the parent for the vaccine or the administration fee.

Option 2: The provider can administer private stock vaccines and bill the primary insurance carrier for both the cost of the vaccine and the administration fee.

Considerations:

- Provider may be reimbursed a higher dollar amount if privately purchased vaccine is administered and both the vaccine and the administration fee are billed to the primary insurer.

Child's Insurance Status	VFC-Eligible?	VFC Eligibility Category
Enrolled in Medicaid	Yes	Medicaid (V02).
Has private health insurance plan with Medicaid as secondary Insurance.	Yes	Medicaid (V02). The provider should choose the option that is most cost-effective for the family.
Has health insurance covering all vaccines but has not yet met plan's deductible or paid for other services received at visit.	No	Insured (V01). This applies even when primary insurer would deny reimbursement for the cost of the vaccine and its administration because the plan's deductible has not been met.
Has health insurance covering all vaccines but has not yet met plan's deductible or paid for other services received at visit and has Medicaid as secondary insurance.	Yes	Medicaid (V02).
Has health insurance covering all vaccines, but the plan has a fixed dollar limit or cap on amount that it will cover.	Yes	Insured (V01) until the fixed dollar limit is met. Underinsured (V05) after the fixed dollar limit is reached.
Has an insurance plan that does not cover all ACIP-recommended vaccines.	Yes	Underinsured (V05). Child can only receive vaccines not covered by the plan.
Has health insurance, but plan does not cover any vaccines.	Yes	Underinsured (V05). With implementation of ACA, this situation should be rare.
Has no health insurance coverage.	Yes	Uninsured (V03).
Has private health insurance that covers all vaccinations and is AI/AN.	Yes	AI/AN (V04). The provider should choose the eligibility category most cost effective for the family.
Has Medicaid and is AI/AN.	Yes	Medicaid (V02) or AI/AN (V04). Providers should use Medicaid for the administration fee (least out-of-pocket expense for family).

No Charge for Vaccines*

- Patient cannot be charged for publicly purchased vaccine.
- Do not bill any individual or other third-party payer for the cost of VFC-supplied or other vaccines purchased through CDC federal contracts.

Administration Fees

- Bill only Medicaid for the administration fee for VFC-eligible children enrolled in Medicaid.
  - Administration fees are per vaccine and not per antigen.
- The vaccine administration fee for **non-Medicaid** VFC-eligible children **must not** exceed $23.87 per dose.
- VFC providers may issue a single bill for the administration fee for **non-Medicaid** VFC-eligible children within 90 days of vaccine administration.
- Unpaid VFC vaccine administration fees may not be sent to collections and VFC providers **may not refuse** to vaccinate an eligible child whose parents have unpaid vaccine administration fees.

Vaccine Management

- Providers should follow VFC storage and handling requirements based on CDC's Vaccine Storage and Handling Toolkit including:
  - Ordering vaccines.
  - Utilizing required equipment.
  - Digital data loggers.
  - Vaccine cold chain.

Vaccine Management Plan

Contact info for current primary and backup vaccine coordinators.	Proper storage and handling practices.	Procedures for vaccine ordering, receiving, inventory control, stock rotation, and handling vaccine loss and waste.	Procedures for emergency situations (transport, equipment malfunction, power failure, and natural disaster).	Documented training related to vaccine management.	Provider and vaccine coordinator roles & responsibilities.

Plans must be updated annually or more frequently as needed.

Vaccine Management: Ordering Vaccine

Vaccine ordering is completed through I-CARE.

Should be up-to-date before submitting an order:

- Patient immunization records.
- Temperature logs for all appliances.
- All data logger certificates of calibration are valid and not expired.
- All temperature excursions must have a vaccine incident report on file.
- No expired vaccines are showing in the clinic's inventory.
- The clinic's inventory in I-CARE matches the physical inventory.
- The clinic's inventory in I-CARE is not showing any negative balances.
- Clinic must be open at least three days a week with at least four consecutive hours a day to be able to receive a delivery.
  - Delivery hours must be entered and updated in I-CARE, including specifying lunch hours or other closures, when placing orders.

Vaccine Management: Ordering Vaccine

- Order and stock enough vaccine to meet patient demand for one to three months.
  - Consider patient numbers, patient age, vaccine uptake, etc.
  - Smaller, more frequent orders help reduce the impact of incidents that may contribute to vaccine loss. **Providers may order as often as necessary**.
- Ensure each VFC vaccine administered is entered into I-CARE. Options are:
  - Direct entry
  - Electronic transmission to I-CARE from an electronic health record (EHR)

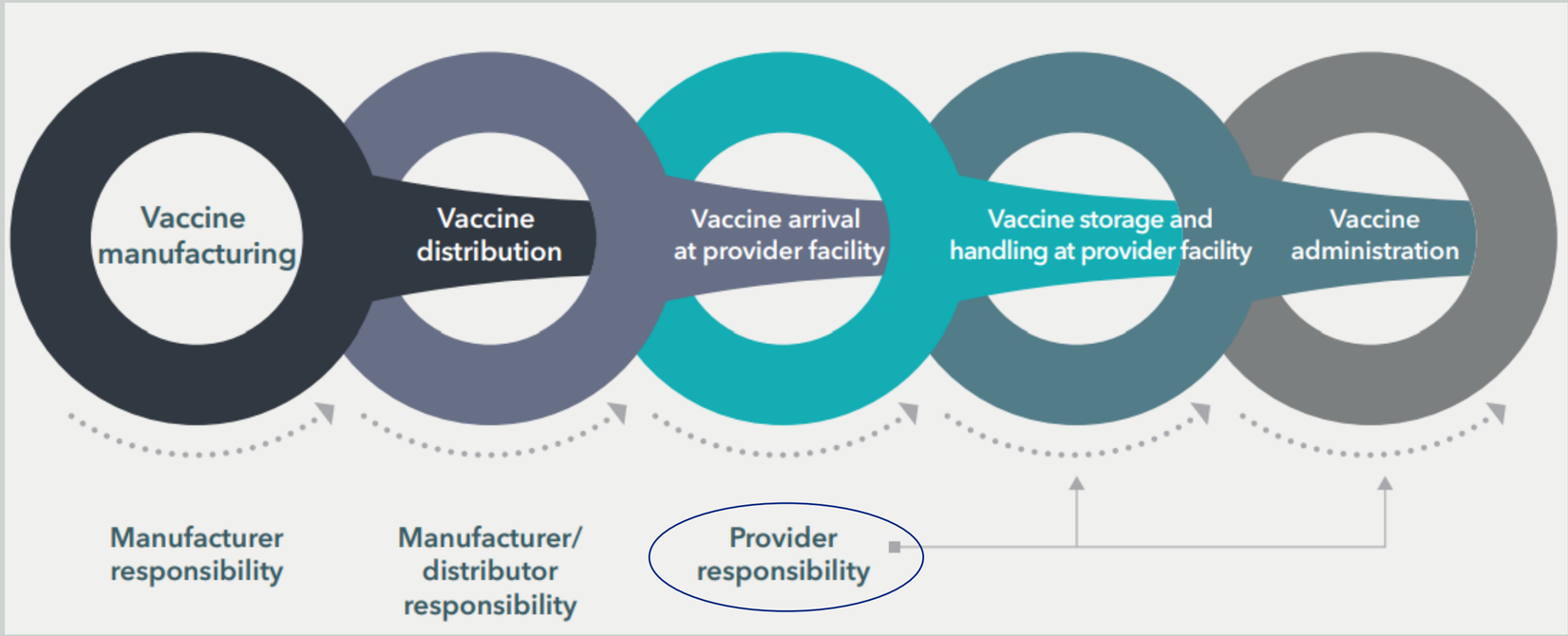
To set EHR to transmit data to I-CARE: DPH.HL7ICARE@Illinois.gov

Vaccine Management: Borrowing Vaccine

- Borrowing between public VFC & private vaccine inventory is not allowed.
- Transfers of VFC vaccine between VFC clinics **are** allowable with permission from IDPH VFC Program and proper transport storage equipment.
    - A transfer request form is available in I-CARE.

Vaccine Management: Cold Chain

- Vaccine cold chain must be maintained (ensures potency and useability).
  - Helps save money and avoid re-vaccination.



Vaccine appearance is NOT a reliable indicator that vaccines have been stored in appropriate conditions.

Vaccine Management: Receiving Vaccine

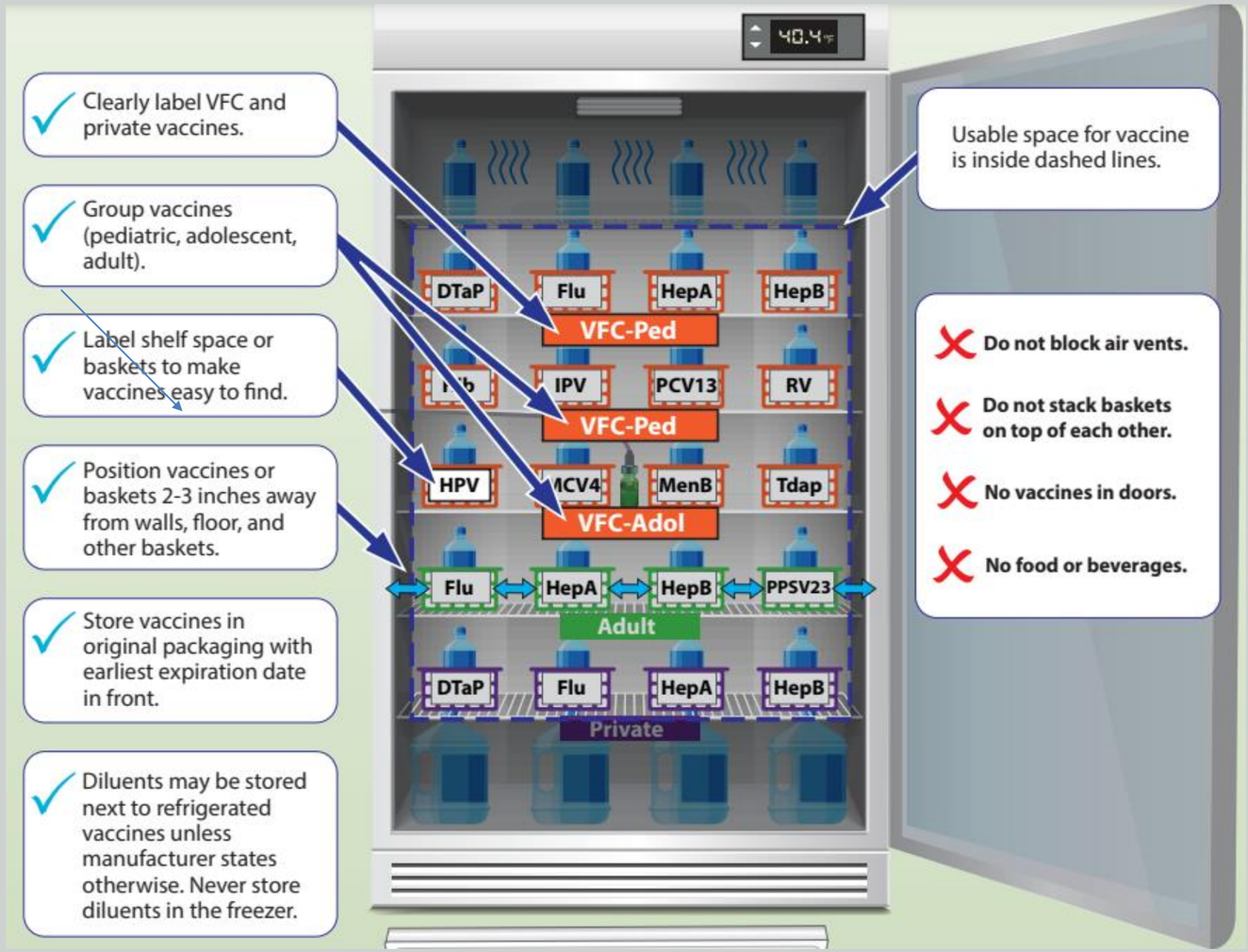
- Vaccine & diluent should be immediately unpacked, stored at recommended temperatures, and documented upon arrival.
  - Do not store shipment box in vaccine storage unit – the combined storage methods may be too cold.

- Check immediately for:
  - Physical damage of shipping container.
  - Correct products were received
  - Diluent and Vaccine expiration dates.
  - Cold chain monitor, if included.

Any issues should be reported within two hours to the Illinois VFC Program Services Staff at 217-785-1455.

Vaccine Management: Storing Vaccine

- Store vaccine by funding type (check I-CARE or packing slips).
- Separate units are not required.
  - VFC: VFC eligible patients only.
  - 317: 317-eligible adults or approved outbreak response.



https://eziz.org/assets/docs/IMM-963.pdf

Vaccine Management: Storing Vaccine

- Stock rotation and removal:
  - Rotate vaccine stock so the vials with the soonest expiration date are at the front (used first).
  - Immediately remove expired vaccine from stock.

TIP: Determine regular intervals for rotation (i.e., weekly), including when there is a vaccine delivery.

Vaccine Management: Required Equipment

- Purpose-built or pharmaceutical-grade refrigerators and freezers are preferred.
  - Still needs to be approved and met with the guidelines and re-certified by approved source.
  - Stand-alone refrigerator and freezer units may also be used.
  - **The Department does not allow combination household refrigerator/freezer units for the storage of vaccines obtained through the VFC program.**
  - **Never store vaccine in a dorm-style or bar-style combined refrigerator/freezer unit.**

Vaccine Management: Required Equipment

- Some purpose-built units separate public & private vaccine stock electronically.
  - If electronic, an inventory printout must be available upon request.

- Power Supply:
  - Plug in only one storage unit per electrical outlet
  - Use a safety-lock plug or an outlet cover.
  - Post “DO NOT UNPLUG” warning signs at outlets and on storage units.
  - Label fuses and circuit breakers to alert others not to turn off these units.
  - Use caution when using power outlets that can be tripped or switched off and avoid using:
    - Built-in circuit switches (may have reset buttons).
    - Outlets that can be activated by a wall switch.
    - Multioutlet power strips.

Vaccine Management: Required Equipment Cont.

- Storage units should be placed in a well-ventilated room, between 68°F - 77°F, and without anything blocking them.
  - Refrigerators should maintain temps between 2° C - 8° C (36°F - 46°F).
  - Freezers should maintain temps between -50° C and -15° C (-58°F - +5°F).
  - Recommended to set temps in Celsius and record to 1 decimal place.
  - Temperatures should be recorded any time staff are in the clinic, at least 3x/week.
  - Record the current temp 2x/day and the min/max temps at the start of every day.
  - Doors should always remain closed – consider using locks or alarms.

- It can take multiple days to stabilize the temp in a new or repaired unit.
  - Min and max temps should be recorded 2x/day for 2 to 7 days.
  - Once two consecutive days of temperatures are recorded within the recommended range, the unit is stable and ready for use.

Vaccine Management: Required Equipment Cont.

- Vaccines should be stored in their original packaging with lids closed.
  - Food and beverages should never be stored in the same unit as vaccines.
  - Water bottles can be used in vaccine storage units to help stabilize the temperature.
  - Water bottles are not recommended for use with certain pharmaceutical-grade and purpose-built units. For such units, follow the manufacturer’s guidance.

Vaccine Management: Digital Data Loggers

- Digital Data Loggers (DDLs) are required to continually monitor the temperature of vaccine.
  - Must have a valid Certificate of Calibration Testing (some units have DDLs built in).
- Data from DDLs is retrieved using special software or a website.
  - Data should be downloaded and reviewed at least weekly.
  - Records should be kept for three years.
- **A back-up DDL must be available in case another fails; calibration testing is required.**

Vaccine Management: Digital Data Loggers Cont.

- All data loggers must have a certificate of calibration that is current (based on the manufacturer's recommended re-testing timeline as indicated on the certificate of calibration).
- Some purpose-built units have built-in DDLs. The purpose-built unit DDLs must meet the same requirements as DDLs for other VFC storage units

- A back-up DDL must be available in case another fails or for emergency transportation.
  - Calibration testing is required.
  - Should have a different calibration testing date than other DDLs so they do not all go through testing at the same time.

Vaccine Management: Digital Data Loggers Cont.

The DDL must be equipped with:

- A temperature probe or sensor.
- An active temperature display outside the unit that can be easily read without opening the unit's door.
- Continuous temperature monitoring and recording capabilities and capacity to routinely download data.

Additional recommended DDL features:

- Alarm for out-of-range temperatures
- Temperature display showing current, minimum, and maximum temperatures
- Low battery indicator
- Accuracy of +/-1°F (0.5°C)
- User-programmable logging interval (or reading rate) recommended at a maximum time interval of no less frequently than every 30 minutes.

Vaccine Management: Digital Data Loggers Cont.

Certificates of Calibration Testing must include:

- Model/device number.
- Serial number.
- Date of calibration (report or issue date).
- Confirmation the instrument passed testing (or instrument in tolerance).

Certificates of calibration must indicate at least one of the following items:

- Conforms to ISO 17025.
- Testing was performed by an ILAC/MRS Signatory body accredited laboratory.
- Is traceable to the standards maintained by NIST.
- Meets specifications and testing requirements for the American Society for Testing and Materials (ASTM) Standard E2877 tolerance Class F (0.5 °C) or better.

Temperature Excursions

- Any temperature reading outside the recommended ranges in the manufacturers' package inserts.
  - Manufacturers will help determine if vaccine is still viable after an excursion.
- Providers should immediately review their storage and handling policies and take the appropriate actions.
- Complete the Vaccine Incident Report in I-CARE.
- Unsure if an excursion occurred?
  - Mark vaccine "DO NOT USE!"
  - Do not use or discard until manufacturer determines viability and IDPH VFC is contacted.

Vaccine Emergency Response

- Onsite generators or backup batteries can be used to prevent transporting vaccines to another storage facility in the event of an emergency like a power outage.
  - If the unit breaks down, then it may be appropriate to transport.

- Generators and backups should be tested quarterly.

Expired, Spoiled, Wasted Vaccine

- Expired, spoiled, and wasted vaccine must be reported in I-CARE within one week of the expiration date.
- Expired and spoiled vaccines in unopened vials or unused manufacturer pre-filled syringes should be returned to McKesson Specialty within 6 months of expiration date for Excise Tax Credit.
    - Must be unopened and in the original manufacturer vial or prefilled syringe.
- Wasted vaccines must be disposed of according to usual medical biosafety procedures, and according to your agency procedures.
    - May include open vials or prefilled syringes with or without the needles attached, vaccine that was drawn into a syringe, or vaccines compromised due to a dropped or broken container.

Transferring Vaccines

- Vaccine can occasionally be transferred between providers in these cases:
  - Vaccine is six months or less from outdate, and unable to be used by provider.
  - Area outbreak resulting in unexpected surge of walk-in patients.
  - Clinic closure requiring transfer of vaccines to other VFC providers.
  - Seasonal clinic needing to transfer vaccine to other VFC providers when closing.
- The following transfer requests will be reviewed on a case-by-case basis:
  - Vaccines are more than six months from the expiration date.
  - The provider has an immediate need for a couple of doses of vaccine before an order could be received.

- Cold chain must be maintained – required to use DDL when transferring.
- Department must review & approve transfer requests.
- Influenza vaccine cannot be transferred.

Mobile Clinics

- Same VFC storage requirements with a permanently installed unit.
  - Mobile clinic should be plugged into a power source at home site location when not in use.
  - Will be inspected as part of compliance visit.
  - Vaccine cannot be transported to city of Chicago or out-of-state.
  - Vaccine must be delivered to home site.

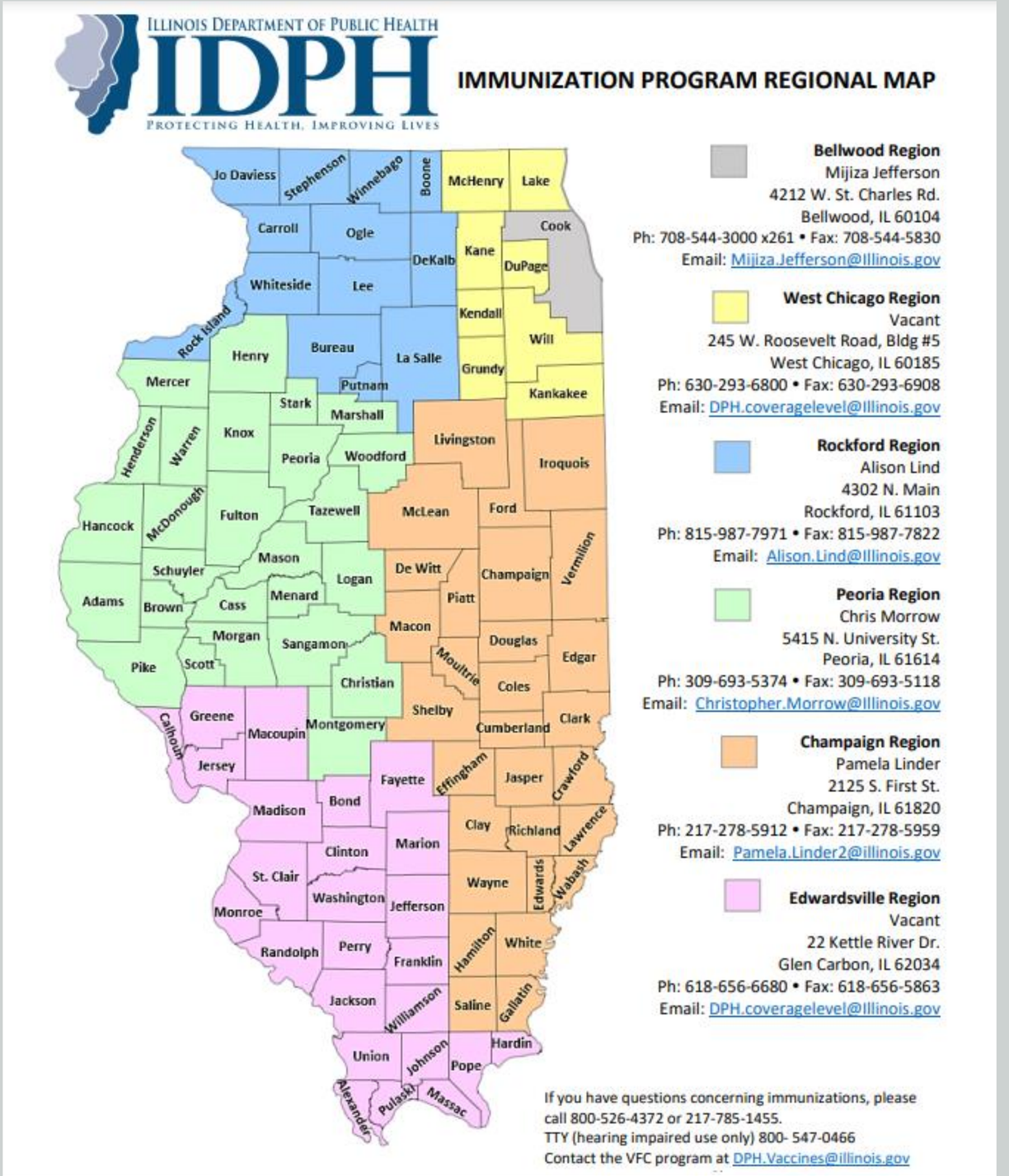
Temporary Off-Site Vaccine Clinics

- Temporary off-site clinics can be held.
  - Transportation, storage, and handling must meet VFC program guidelines.
  - Vaccine must be delivered to permanent location.
  - Total time for travel + clinic day should not exceed 8 hours (e.g. if transport to an off-site clinic is 1 hour each way, the clinic may run for up to 6 hours).
  - When transporting vaccines, use a portable vaccine refrigerator or freezer unit or qualified container and packout that maintains appropriate storage temperatures.
  - Use of the manufacturer shipping container or a frozen water bottle transport system is not permitted for transport to temporary, mobile, or off-site clinics.
  - Vaccine must be returned to permanent location & DDLs must be reviewed to ensure proper temperatures were maintained.

An off-site vaccine clinic notification form must be submitted in I-CARE 48 hours prior to the event.

Contacts

- Contact the VFC program at DPH.Vaccines@illinois.gov



Break

Please return by 10:15

SESSION 2:
VACCINE SCHEDULES

Sharon Hovey, MD, FAAP

- Pediatrician
- University North Dakota
- Naperville, Illinois

Learning Objectives:

After this session participants will be able to

1

Outline new vaccine products and updates.

2

Apply the 2023 Advisory Committee on Immunizations Practices (ACIP) pediatric vaccination and catch-up schedules.

3

Summarize current routine immunization rates.

Requirements

VFC providers must comply with:

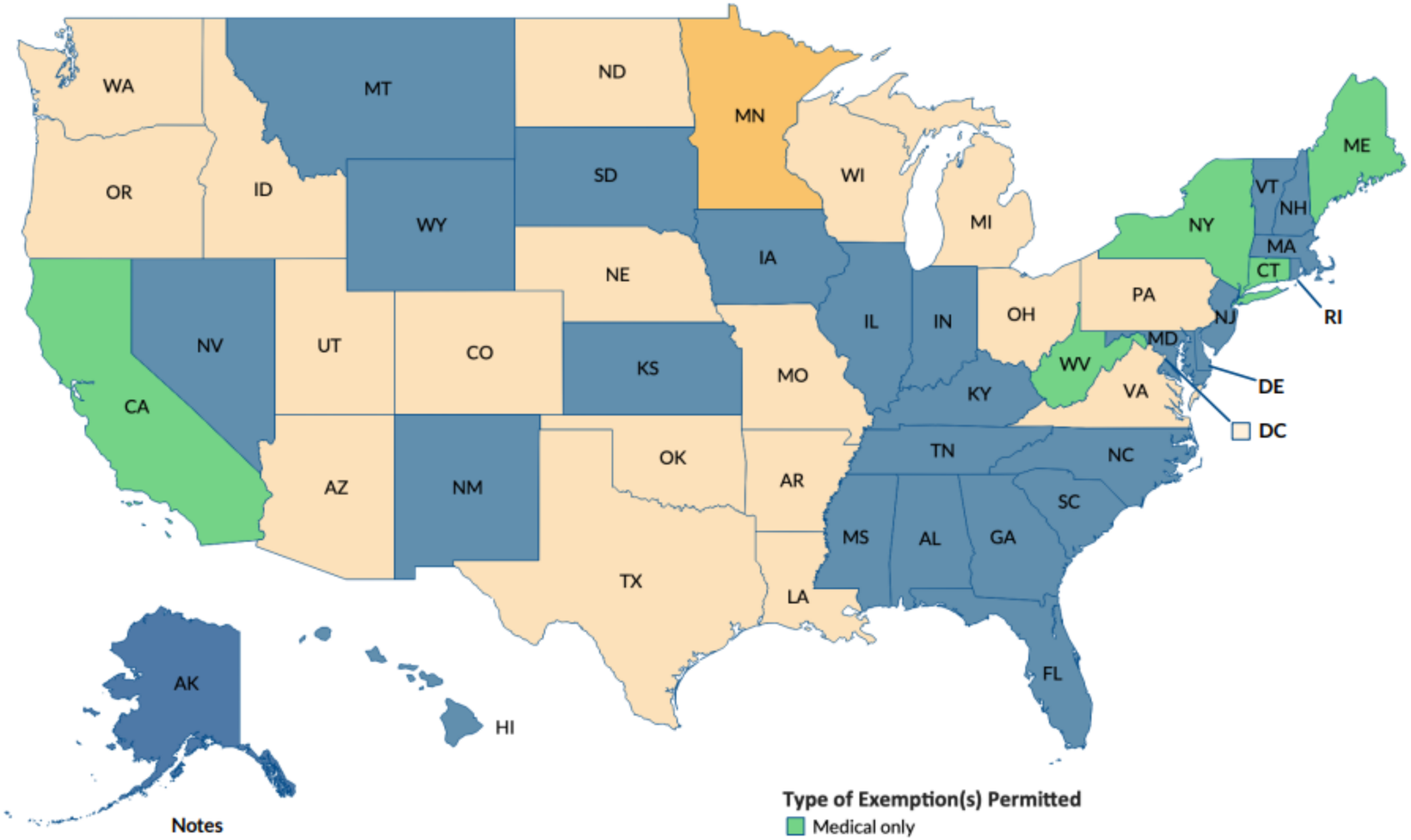
- Current ACIP recommendations and VFC resolutions.
- Making vaccines identified in the Provider Profile based on the provider type and population served available including non-routine vaccines.
- Understanding state laws related to vaccination requirements and acceptable vaccine exemptions.
- Using ACIP recommendations and vaccine package inserts to understand contraindications for each vaccine type available through the VFC program.

State Vaccination Requirements

- State laws establish vaccination requirements for school children.
  - Laws often apply to public schools, private schools and day care facilities.
- Tools for maintaining high vaccination coverage rates.
- State laws also establish mechanisms for enforcement.
  - Documentation, signatures, etc.
- All states provide medical exemptions.
  - Some state offer religious and/or philosophical exemptions.

Exemptions Permitted for State Childcare and School (Kg–Gr 12) Immunization Requirements

March 2023



Notes

AZ: Religious exemption for childcare only, personal belief exemption for school (Kg-Gr 12) only
CO: Religious and personal belief exemptions combined under category of "nonmedical exemption"
DC and VA: Personal belief exemption for HPV only
MO and NE: Personal belief exemption for childcare only
WA: Personal belief exemption not allowed for MMR

Type of Exemption(s) Permitted

- Medical only
- Medical, religious
- Medical, personal belief
- Medical, religious, personal belief

Immunize.org

Source: state immunization programs
For details, see data table: www.immunize.org/laws/exemptions.asp

https://www.immunize.org/laws/exemptions.pdf

IL Requirements

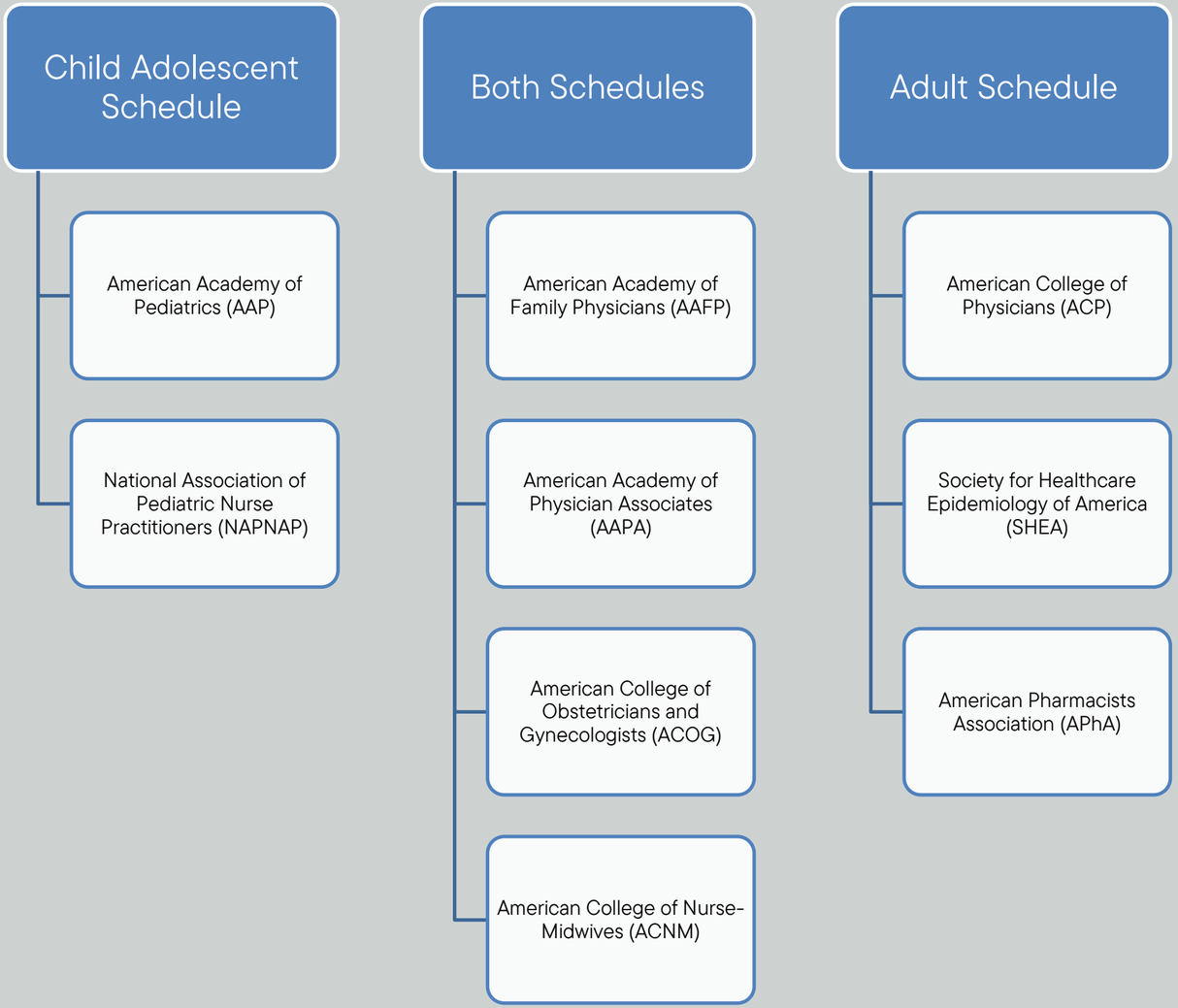
- Medical and religious exemptions.
- 105 Ill. Comp. Stat. Ann. 5/27-8.1; Ill. Adm. Code tit. 77, § 665.240; Ill. Adm. Code tit. 77, § 665.510; Ill. Adm. Code tit. 77, § 665.520; Ill. Adm. Code tit. 77, § Adm. Code 698.50.

ACIP

- Establishes:
  - Age for vaccine recommendation.
  - Number of doses and dosing interval.
  - Precautions and contraindications.
  - Technical recommendations on vaccine use and immunization practices
  - Approves vaccines provided through VFC program.

Recommendations on the CDC's website.

ACIP Schedule - Approving Partners



VFC-ACIP Resolutions

ACIP votes on a resolution to include the vaccine change in the VFC program.

VFC resolutions passed by ACIP form the basis for VFC program policies on vaccine availability and use.

Vaccines procured through the VFC program must be administered according to the guidelines outlined by ACIP in VFC resolutions (and in accordance with state laws).

CDC establishes contracts for VFC vaccines only after a VFC resolution is in place.

VFC-ACIP Vaccine Resolutions

Print

Vaccine procured through the VFC program must be administered according to the guidelines outlined by the ACIP in VFC resolutions. VFC vaccine also may be administered in accordance with State school attendance laws.

- 10/22-1 COVID-19 [1 page] Updated Oct 2022
- 6/21-1 Dengue [1 page] Updated Jun 2021
- 10/19-1 Diphtheria, Tetanus, & Pertussis [4 pages, 508] Updated Oct 2019
- 6/19-2 *Haemophilus influenzae* type b [3 pages] Updated Jul 2019
- 6/19-6 Hepatitis A [2 pages] Updated Jul 2019
- 6/19-3 Hepatitis B [4 pages] Updated Jul 2019
- 10/16-2 Human Papillomavirus (HPV) [2 pages]
- 6/23-1 Influenza [3 pages] Updated Jul 2023
- 6/20-1 Meningococcal [4 pages] Updated Oct 2022
- 10/17-3 MMR & Varicella [3 pages] Updated Jun 2022
- 06/94-16 Outbreak controls [1 page]
- 06/23-2 Pneumococcal [4 pages] Updated Jul 2023
- 6/19-4 Polio [2 pages] Updated Jul 2019
- 06/08-1 Rotavirus [3 pages] Updated Feb 2023
- 08/23-1 RSV [2 pages] Updated Aug 2023
- 08/23-2 Vaccines included in VFC Program [1 page] Updated Aug 2023

PACKAGE INSERTS on FDA website

Immunization Schedules – Why They Matter

- There are no other alternative studied immunization schedule approve to provide to our patients.
- Protection against roughly 20 different life-threatening diseases.
- Prevention/control of infectious disease outbreaks.
- Gives children protection when they are most vulnerable.

Using the ACIP Schedule

To make vaccination recommendations, healthcare providers should:

1. Determine needed vaccines based on age (Table 1).
2. Determine appropriate intervals for catch-up, if needed (Table 2).
3. Assess for medical conditions and other indications (Table 3).
4. Review special situations (Vaccination Notes).
5. Review contraindications and precautions to vaccination (Appendix).

Table 1

*There is no other alternative studied immunization schedule

Table 1 Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2023

These recommendations must be read with the notes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars.
To determine minimum intervals between doses, see the catch-up schedule (Table 2).

Vaccine	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos	18 mos	19–23 mos	2–3 yrs	4–6 yrs	7–10 yrs	11–12 yrs	13–15 yrs	16 yrs	17–18 yrs
Hepatitis B (HepB)	1st dose	◄---- 2nd dose ----►			◄---------- 3rd dose ----------►												
Rotavirus (RV): RV1 (2-dose series), RV5 (3-dose series)			1st dose	2nd dose	See Notes												
Diphtheria, tetanus, acellular pertussis (DTaP <7 yrs)			1st dose	2nd dose	3rd dose			◄---- 4th dose ----►				5th dose					
Haemophilus influenzae type b (Hib)			1st dose	2nd dose	See Notes		◄-- 3rd or 4th dose, See Notes --►										
Pneumococcal conjugate (PCV13, PCV15)			1st dose	2nd dose	3rd dose		◄---- 4th dose ----►										
Inactivated poliovirus (IPV <18 yrs)			1st dose	2nd dose	◄---------- 3rd dose ----------►							4th dose					See Notes
COVID-19 (1vCOV-mRNA, 2vCOV-mRNA, 1vCOV-aPS)					2- or 3- dose primary series and booster (See Notes)												
Influenza (IIV4)					Annual vaccination 1 or 2 doses								or	Annual vaccination 1 dose only			
or																	
Influenza (LAIV4)											Annual vaccination 1 or 2 doses			Annual vaccination 1 dose only			
Measles, mumps, rubella (MMR)					See Notes		◄---- 1st dose ----►					2nd dose					
Varicella (VAR)							◄---- 1st dose ----►					2nd dose					
Hepatitis A (HepA)					See Notes		2-dose series, See Notes										
Tetanus, diphtheria, acellular pertussis (Tdap ≥7 yrs)														1 dose			
Human papillomavirus (HPV)														See Notes			
Meningococcal (MenACWY-D ≥9 mos, MenACWY-CRM ≥2 mos, MenACWY-TT ≥2years)			See Notes											1st dose		2nd dose	
Meningococcal B (MenB-4C, MenB-FHbp)														See Notes			
Pneumococcal polysaccharide (PPSV23)											See Notes						
Dengue (DEN4CYD; 9-16 yrs)														Seropositive in endemic dengue areas (See Notes)			

Range of recommended ages for all children
Range of recommended ages for catch-up vaccination
Range of recommended ages for certain high-risk groups
Recommended vaccination can begin in this age group
Recommended vaccination based on shared clinical decision-making
No recommendation/ not applicable

https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf

Table 2

Table 2 Recommended Catch-up Immunization Schedule for Children and Adolescents Who Start Late or Who Are More than 1 Month Behind, United States, 2023

The table below provides catch-up schedules and minimum intervals between doses for children whose vaccinations have been delayed. A vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Use the section appropriate for the child's age. **Always use this table in conjunction with Table 1 and the Notes that follow.**

Vaccine	Minimum Age for Dose 1	Minimum Interval Between Doses			
		Dose 1 to Dose 2	Dose 2 to Dose 3	Dose 3 to Dose 4	Dose 4 to Dose 5
Children age 4 months through 6 years					
Hepatitis B	Birth	**4 weeks**	**8 weeks *and* at least 16 weeks after first dose** minimum age for the final dose is 24 weeks		
Rotavirus	6 weeks Maximum age for first dose is 14 weeks, 6 days.	**4 weeks**	**4 weeks** maximum age for final dose is 8 months, 0 days		
Diphtheria, tetanus, and acellular pertussis	6 weeks	**4 weeks**	**4 weeks**	**6 months**	**6 months**
Haemophilus influenzae type b	6 weeks	**No further doses needed** if first dose was administered at age 15 months or older. **4 weeks** if first dose was administered before the 1st birthday. **8 weeks (as final dose)** if first dose was administered at age 12 through 14 months.	**No further doses needed** if previous dose was administered at age 15 months or older **4 weeks** if current age is younger than 12 months ***and*** first dose was administered at younger than age 7 months ***and*** at least 1 previous dose was PRP-T (ActHib®, Pentacel®, Hiberix®), Vaxelis® or unknown **8 weeks *and* age 12 through 59 months (as final dose)** if current age is younger than 12 months ***and*** first dose was administered at age 7 through 11 months; OR if current age is 12 through 59 months ***and*** first dose was administered before the 1st birthday ***and*** second dose was administered at younger than 15 months; OR if both doses were PedvaxHIB® and were administered before the 1st birthday	**8 weeks (as final dose)** This dose only necessary for children age 12 through 59 months who received 3 doses before the 1st birthday.	
Pneumococcal conjugate	6 weeks	**No further doses needed** for healthy children if first dose was administered at age 24 months or older **4 weeks** if first dose was administered before the 1st birthday **8 weeks (as final dose for healthy children)** if first dose was administered at the 1st birthday or after	**No further doses needed** for healthy children if previous dose was administered at age 24 months or older **4 weeks** if current age is younger than 12 months and previous dose was administered at <7 months old **8 weeks (as final dose for healthy children)** if previous dose was administered between 7–11 months (wait until at least 12 months old); OR if current age is 12 months or older and at least 1 dose was administered before age 12 months	**8 weeks (as final dose)** this dose is only necessary for children aged 12 through 59 months regardless of risk, or age 60 through 71 months with any risk, who received 3 doses before age 12 months.	
Inactivated poliovirus	6 weeks	**4 weeks**	**4 weeks** if current age is <4 years **6 months (as final dose)** if current age is 4 years or older	**6 months (minimum age 4 years for final dose)**	
Measles, mumps, rubella	12 months	**4 weeks**			
Varicella	12 months	**3 months**			
Hepatitis A	12 months	**6 months**			
Meningococcal ACWY	2 months MenACWY-CRM 9 months MenACWY-D 2 years MenACWY-TT	**8 weeks**	See Notes	See Notes	
Children and adolescents age 7 through 18 years					
Meningococcal ACWY	Not applicable (N/A)	**8 weeks**			
Tetanus, diphtheria; tetanus, diphtheria, and acellular pertussis	7 years	**4 weeks**	**4 weeks** if first dose of DTaP/DT was administered before the 1st birthday **6 months (as final dose)** if first dose of DTaP/DT or Tdap/Td was administered at or after the 1st birthday	**6 months** if first dose of DTaP/DT was administered before the 1st birthday	
Human papillomavirus	9 years	**Routine dosing intervals are recommended.**			
Hepatitis A	N/A	**6 months**			
Hepatitis B	N/A	**4 weeks**	**8 weeks *and* at least 16 weeks after first dose**		
Inactivated poliovirus	N/A	**4 weeks**	**6 months** A fourth dose is not necessary if the third dose was administered at age 4 years or older and at least 6 months after the previous dose.	A fourth dose of IPV is indicated if all previous doses were administered at <4 years or if the third dose was administered <6 months after the second dose.	
Measles, mumps, rubella	N/A	**4 weeks**			
Varicella	N/A	**3 months** if younger than age 13 years. **4 weeks** if age 13 years or older			
Dengue	9 years	**6 months**	6 months		

https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf

Table 3

Table 3 Recommended Child and Adolescent Immunization Schedule by Medical Indication, United States, 2023

Always use this table in conjunction with Table 1 and the Notes that follow.

VACCINE	INDICATION									
	Pregnancy	Immunocompromised status (excluding HIV infection)	HIV infection CD4+ count[a]: <15% or total CD4 cell count of <200/mm³	HIV infection CD4+ count[a]: ≥15% and total CD4 cell count of ≥200/mm³	Kidney failure, end-stage renal disease, or on hemodialysis	Heart disease or chronic lung disease	CSF leak or cochlear implant	Asplenia or persistent complement component deficiencies	Chronic liver disease	Diabetes
Hepatitis B										
Rotavirus		SCID[b]								
Diphtheria, tetanus, and acellular pertussis (DTaP)										
Haemophilus influenzae type b										
Pneumococcal conjugate										
Inactivated poliovirus										
COVID-19		See Notes	See Notes							
Influenza (IIV4)										
or										
Influenza (LAIV4)						Asthma, wheezing: 2–4yrs[c]				
Measles, mumps, rubella	*									
Varicella	*									
Hepatitis A										
Tetanus, diphtheria, and acellular pertussis (Tdap)										
Human papillomavirus	*									
Meningococcal ACWY										
Meningococcal B										
Pneumococcal polysaccharide										
Dengue										

Vaccination according to the routine schedule recommended

Recommended for persons with an additional risk factor for which the vaccine would be indicated

Vaccination is recommended, and additional doses may be necessary based on medical condition or vaccine. See Notes.

Precaution–vaccine might be indicated if benefit of protection outweighs risk of adverse reaction

Contraindicated or not recommended–vaccine should not be administered

*Vaccinate after pregnancy

No recommendation/not applicable

a. For additional information regarding HIV laboratory parameters and use of live vaccines, see the *General Best Practice Guidelines for Immunization*, "Altered Immunocompetence," at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html and Table 4-1 (footnote J) at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.
b. Severe Combined Immunodeficiency
c. LAIV4 contraindicated for children 2–4 years of age with asthma or wheezing during the preceding 12 months

https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf

Notes

Appendix

Notes

Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2023

For vaccination recommendations for persons ages 19 years or older, see the Recommended Adult Immunization Schedule, 2023.

Additional information

- Consult relevant ACIP statements for detailed recommendations at www.cdc.gov/vaccines/hcp/acip-recs/index.html.
- For calculating intervals between doses, 4 weeks = 28 days. Intervals of ≥4 months are determined by calendar months.
- Within a number range (e.g., 12–18), a dash (–) should be read as "through."
- Vaccine doses administered ≤4 days before the minimum age or interval are considered valid. Doses of any vaccine administered ≥5 days earlier than the minimum age or minimum interval should not be counted as valid and should be repeated as age appropriate. **The repeat dose should be spaced after the invalid dose by the recommended minimum interval.** For further details, see Table 3-2, Recommended and minimum ages and intervals between vaccine doses, in *General Best Practice Guidelines for Immunization* at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html.
- Information on travel vaccination requirements and recommendations is available at www.cdc.gov/travel/.
- For vaccination of persons with immunodeficiencies, see Table 8-1, Vaccination of persons with primary and secondary immunodeficiencies, in *General Best Practice Guidelines for Immunization* at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html, and Immunization in Special Clinical Circumstances (In: Kimberlin DW, Barnett ED, Lynfield Ruth, Sawyer MH, eds. *Red Book: 2021–2024 Report of the Committee on Infectious Diseases*. 32nd ed. Itasca, IL: American Academy of Pediatrics; 2021:72–86).
- For information about vaccination in the setting of a vaccine-preventable disease outbreak, contact your state or local health department.
- The National Vaccine Injury Compensation Program (VICP) is a no-fault alternative to the traditional legal system for resolving vaccine injury claims. All vaccines included in the child and adolescent vaccine schedule are covered by VICP except dengue, PPSV23, and COVID-19 vaccines. COVID-19 vaccines that are authorized or approved by the FDA are covered by the Countermeasures Injury Compensation Program (CICP). For more information, see www.hrsa.gov/vaccinecompensation or www.hrsa.gov/cicp.

COVID-19 vaccination
(minimum age: 6 months [Moderna and Pfizer-BioNTech COVID-19 vaccines], 12 years [Novavax COVID-19 Vaccine])

Routine vaccination

- **Primary series:**
  - **Age 6 months–4 years:** 2-dose series at 0, 4-8 weeks (Moderna) or 3-dose series at 0, 3-8, 11-16 weeks (Pfizer-BioNTech)
  - **Age 5–11 years:** 2-dose series at 0, 4-8 weeks (Moderna) or 2-dose series at 0, 3-8 weeks (Pfizer-BioNTech)
  - **Age 12–18 years:** 2-dose series at 0, 4-8 weeks (Moderna) or 2-dose series at 0, 3-8 weeks (Novavax, Pfizer-BioNTech)
- For **booster dose recommendations** see www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html

Special situations

Persons who are moderately or severely immunocompromised

- **Primary series**
  - **Age 6 months–4 years:** 3-dose series at 0, 4, 8 weeks (Moderna) or 3-dose series at 0, 3, 11 weeks (Pfizer-BioNTech)
  - **Age 5–11 years:** 3-dose series at 0, 4, 8 weeks (Moderna) or 3-dose series at 0, 3, 7 weeks (Pfizer-BioNTech)
  - **Age 12–18 years:** 3-dose series at 0, 4, 8 weeks (Moderna) or 2-dose series at 0, 3 weeks (Novavax) or 3-dose series at 0, 3, 7 weeks (Pfizer-BioNTech)
- **Booster dose:** see www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html
- **Pre-exposure prophylaxis** (monoclonal antibodies) may be considered to complement COVID-19 vaccination. See www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#immunocompromised

For Janssen COVID-19 Vaccine recipients see COVID-19 schedule at www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html

Note: Administer an age-appropriate vaccine product for each dose. Current COVID-19 schedule and dosage formulation available at www.cdc.gov/vaccines/covid-19/downloads/COVID-19-immunization-schedule-ages-6months-older.pdf. For more information on Emergency Use Authorization (EUA) indications for COVID-19 vaccines, see www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines.

Dengue vaccination
(minimum age: 9 years)

Routine vaccination

- Age 9–16 years living in areas with endemic dengue **AND** have laboratory confirmation of previous dengue infection
  - 3-dose series administered at 0, 6, and 12 months
- Endemic areas include Puerto Rico, American Samoa, US Virgin Islands, Federated States of Micronesia, Republic of Marshall Islands, and the Republic of Palau. For updated guidance on dengue endemic areas and pre-vaccination laboratory testing see www.cdc.gov/mmwr/volumes/70/rr/rr7006a1.htm?s_cid=rr7006a1_w and www.cdc.gov/dengue/vaccine/hcp/index.html
- Dengue vaccine should not be administered to children traveling to or visiting endemic dengue areas.

Diphtheria, tetanus, and pertussis (DTaP) vaccination
(minimum age: 6 weeks [4 years for Kinrix® or Quadracel®])

Routine vaccination

- 5-dose series at age 2, 4, 6, 15–18 months, 4–6 years
  - **Prospectively:** Dose 4 may be administered as early as age 12 months if at least 6 months have elapsed since dose 3.
  - **Retrospectively:** A 4th dose that was inadvertently administered as early as age 12 months may be counted if at least 4 months have elapsed since dose 3.

Catch-up vaccination

- Dose 5 is not necessary if dose 4 was administered at age 4 years or older and at least 6 months after dose 3.
- For other catch-up guidance, see Table 2.

Special situations

- **Wound management** in children less than age 7 years with history of 3 or more doses of tetanus-toxoid-containing vaccine: For all wounds except clean and minor wounds, administer DTaP if more than 5 years since last dose of tetanus-toxoid-containing vaccine. For detailed information, see www.cdc.gov/mmwr/volumes/67/rr/rr6702a1.htm.

Appendix

Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2023

Guide to Contraindications and Precautions to Commonly Used Vaccines

Adapted from Table 4-1 in Advisory Committee on Immunization Practices (ACIP) General Best Practice Guidelines for Immunization: Contraindication and Precautions available at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html *and ACIP's Recommendations for the Prevention and Control of 2022-23 seasonal influenza with Vaccines available at* www.cdc.gov/mmwr/volumes/71/rr/rr7101a1.htm.

For COVID-19 vaccine contraindications and precautions see www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#contraindications

Vaccine	Contraindicated or Not Recommended[1]	Precautions[2]
Influenza, egg-based, inactivated injectable (IIV4)	• Severe allergic reaction (e.g., anaphylaxis) after previous dose of any influenza vaccine (i.e., any egg-based IIV, ccIIV, RIV, or LAIV of any valency) • Severe allergic reaction (e.g., anaphylaxis) to any vaccine component[3] (excluding egg)	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Moderate or severe acute illness with or without fever
Influenza, cell culture-based inactivated injectable [(ccIV4), Flucelvax® Quadrivalent]	• Severe allergic reaction (e.g., anaphylaxis) to any ccIIV of any valency, or to any component[3] of ccIIV4	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Persons with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of any egg-based IIV, RIV, or LAIV of any valency. If using ccIV4, administer in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions. May consult an allergist. • Moderate or severe acute illness with or without fever
Influenza, recombinant injectable [(RIV4), Flublok® Quadrivalent]	• Severe allergic reaction (e.g., anaphylaxis) to any RIV of any valency, or to any component[3] of RIV4	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Persons with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of any egg-based IIV, ccIIV, or LAIV of any valency. If using RIV4, administer in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions. May consult an allergist. • Moderate or severe acute illness with or without fever
Influenza, live attenuated [LAIV4, Flumist® Quadrivalent]	• Severe allergic reaction (e.g., anaphylaxis) after previous dose of any influenza vaccine (i.e., any egg-based IIV, ccIIV, RIV, or LAIV of any valency) • Severe allergic reaction (e.g., anaphylaxis) to any vaccine component[3] (excluding egg) • Children age 2 –4 years with a history of asthma or wheezing • Anatomic or functional asplenia • Immunocompromised due to any cause including, but not limited to, medications and HIV infection • Close contacts or caregivers of severely immunosuppressed persons who require a protected environment • Pregnancy • Cochlear implant • Active communication between the cerebrospinal fluid (CSF) and the oropharynx, nasopharynx, nose, ear or any other cranial CSF leak • Children and adolescents receiving aspirin or salicylate-containing medications • Received influenza antiviral medications oseltamivir or zanamivir within the previous 48 hours, peramivir within the previous 5 days, or baloxavir within the previous 17 days	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Asthma in persons aged 5 years old or older • Persons with underlying medical conditions (other than those listed under contraindications) that might predispose to complications after wild-type influenza virus infection [e.g., chronic pulmonary, cardiovascular (except isolated hypertension), renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus)] • Moderate or severe acute illness with or without fever

1. When a contraindication is present, a vaccine should NOT be administered. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization. www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html
2. When a precaution is present, vaccination should generally be deferred but might be indicated if the benefit of protection from the vaccine outweighs the risk for an adverse reaction. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization. www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html
3. Vaccination providers should check FDA-approved prescribing information for the most complete and updated information, including contraindications, warnings, and precautions. Package inserts for U.S.-licensed vaccines are available at www.fda.gov/vaccines-blood-biologics/approved-products/vaccines-licensed-use-united-states

Hepatitis B Vaccine

- Recommended for infants born to mothers with positive test result for hepatitis B surface antigen (HBsAg) or unknown status.
- Catch up includes Heplisav-B and PreHevbrio for age 18 years and older.
- Heplisav-B not recommended during pregnancy.

Rotavirus Vaccine

❖ No ACIP preference on brand

- Rotavirus (Rotarix ™)
  - NO RECONSTITUTION NEEDED!
  - Oral-dosing applicator-only presentation.
  - Approved for use in infants 6 weeks old with the max age of the 1st dose at 14 weeks + 6 days of age and the final dose no later than 8 months + 0 days of age.
  - Single 1.5ml dose.
  - Keep in original package to protect from light, store refrigerator 2-8°C.
- RotaTeq RV5
  - RotaTeq is a 3 dose series at age 2, 4, and 6 months.
  - Administered orally starting at 6 to 12 weeks of age, with the subsequent doses administered at 4- to 10-week intervals.
  - Third dose should not be given after 32 weeks of age.

Rotavirus Vaccine

- Rotavirus (Rotarix ™) Changes
  - 2 variations of live vaccine Rotarix available until 2025 when older lyophilized formulation will retire.
  - Use up current 1ml lyophilized formulation (requires reconstitution) prior to using new liquid formulation.
  - New formulation contains disodium adipate & no longer contains sorbitol or phenol red.
  - Clinical trials comparing the 2 formulations showed similar safety profiles.

DTaP

- 5-dose series at age 2, 4, 6, 15–18 months, 4–6 years.
- Prospectively: Dose 4 may be administered as early as age 12 months if at least 6 months have elapsed since dose 3.
- Retrospectively: A 4th dose that was inadvertently administered as early as age 12 months may be counted if at least 4 months have elapsed since dose 3.

Pneumococcal Vaccine

- Pneumococcal conjugate vaccines
  - PCV13 (Prevnar 13, Pfizer) and PCV15 (Vaxneuvance, Merck), interchangeable.
  - PCV20 (Prevnar 20, Pfizer).
  - Either PCV15 or PCV20 may be used for the full series or to complete the recommended schedule begun with PCV13.
  - If only 13-valent PCV (PCV13) is available when the child is scheduled to receive a PCV, PCV13 may be given as previously recommended.

- Pneumococcal polysaccharide vaccine.
  - PPSV23 (Pneumovax23, Merck).

- Pneumococcal Vaccine added to the catch-up schedule, with 8 weeks marking the final dose. Age 12-59 months, regardless of risk.

Polio Vaccine

- Special situations -
  - Adolescents aged 18 years at increased risk of exposure.
    - No evidence of complete polio vaccination series (at least 3 doses) → administer remaining doses to complete a 3-dose series.
    - Evidence of completed polio vaccination series (at least 3 doses) → may administer 1 lifetime IPV booster.

Influenza Vaccine

- Recommended for everyone 6 months+.
- Any licensed influenza vaccine appropriate by age and health status can be used.
- The AAP does not prefer any product over another for children and adolescents with no contraindications.
- Not given to individuals in close contact to immunocompromised people needing a protective environment.
- CAN be given to those with an egg allergy in medical setting where severe allergic reactions can be managed.

Influenza Vaccine

Influenza Vaccine Products for the 2023–2024 Influenza Season

Manufacturer	Trade Name (vaccine abbreviation)[1]	How Supplied	Mercury Content (mcg Hg/0.5mL)	Age Range	CVX Code	Vaccine Product Billing Code[2] CPT
AstraZeneca	FluMist (LAIV4)	0.2 mL (single-use nasal spray)	0	2 through 49 years	149	90672
GSK	Fluarix (IIV4)	0.5 mL (single-dose syringe)	0	6 months & older[3]	150	90686
	FluLaval (IIV4)	0.5 mL (single-dose syringe)	0	6 months & older[3]	150	90686
Sanofi	Flublok (RIV4)	0.5 mL (single-dose syringe)	0	18 years & older	185	90682
	Fluzone (IIV4)	0.5 mL (single-dose syringe)	0	6 months & older[3]	150	90686
		0.5 mL (single-dose vial)	0	6 months & older[3]	150	90686
		5.0 mL multi-dose vial (0.25 mL dose)	25	6 through 35 months[3]	158	90687
		5.0 mL multi-dose vial (0.5 mL dose)	25	6 months & older	158	90688
	Fluzone High-Dose (IIV4-HD)	0.7 mL (single-dose syringe)	0	65 years & older	197	90662
Seqirus	Afluria (IIV4)	5.0 mL multi-dose vial (0.25 mL dose)	24.5	6 through 35 months[3]	158	90687
		5.0 mL multi-dose vial (0.5 mL dose)	24.5	3 years & older	158	90688
		0.5 mL (single-dose syringe)	0	3 years & older[3]	150	90686
	Fluad (aIIV4)	0.5 mL (single-dose syringe)	0	65 years & older	205	90694
	Flucelvax (ccIIV4)	0.5 mL (single-dose syringe)	0	6 months & older[3]	171	90674
		5.0 mL multi-dose vial (0.5 mL dose)	25	6 months & older[3]	186	90756

NOTES

1. IIV4 = egg-based quadrivalent inactivated influenza vaccine (injectable); where necessary to refer to cell culture-based vaccine, the prefix "cc" is used (e.g., ccIIV4); RIV4 = quadrivalent recombinant hemagglutinin influenza vaccine (injectable); aIIV4 = adjuvanted quadrivalent inactivated influenza vaccine.
2. An administration code should always be reported in addition to the vaccine product code. Note: Third party payers may have specific policies and guidelines that might require providing additional information on their claim forms.
3. Dosing for infants and children age 6 through 35 months:
   - Afluria 0.25 mL
   - Fluarix 0.5 mL
   - Flucelvax 0.5 mL
   - FluLaval 0.5 mL
   - Fluzone 0.25 mL or 0.5 mL
4. Afluria is approved by the Food and Drug Administration for intramuscular administration with the PharmaJet Stratis Needle-Free Injection System for persons age 18 through 64 years.

https://www.immunize.org/catg.d/p4072.pdf

MMR

- 2-dose series at age 12–15 months, age 4–6 years.
- MMR or MMRV may be administered.
- Note: For dose 1 in children age 12–47 months, it is recommended to administer MMR and varicella vaccines separately. MMRV may be used if parents or caregivers express a preference.

Varicella

- 2-dose series at age 12–15 months, 4–6 years
- VAR or MMRV may be administered*
- Dose 2 may be administered as early as 3 months after dose 1 (a dose inadvertently administered after at least 4weeks may be counted as valid).
- *Note: For dose 1 in children age 12–47 months, it is recommended to administer MMR and varicella vaccines separately. MMRV may be used if parents or caregivers express a preference.

Hepatitis A

- 2-dose series (minimum interval: 6 months) at age 12–23 months.
- For persons traveling to or working in countries with high or intermediate endemic hepatitis A.
  - Infants age 6–11 months: 1 dose before departure; revaccinate with 2 doses (separated by at least 6 months) between age 12–23 months.
  - Unvaccinated age 12 months or older: Administer dose 1 as soon as travel is considered.

HPV

- Routinely recommended at **age 11–12 years (can start at age 9 years)** and catch-up HPV vaccination recommended for all persons through age 18 years if not adequately vaccinated.
- 2- or 3-dose series depending on age at initial vaccination:
  - **Age 9 –14 years at initial vaccination**: 2-dose series at 0, 6–12 months (minimum interval: 5 months; repeat dose if administered too soon).
  - **Age 15 years+ at initial vaccination:** 3-dose series at 0, 1–2 months, 6 months (minimum intervals: dose 1 to dose 2: 4 weeks / dose 2 to dose 3: 12 weeks / dose 1 to dose 3: 5 months; repeat dose if administered too soon).
- If vaccination schedule is interrupted, the series does not need to be restarted.
- No additional doses recommended.

Meningococcal Vaccines

❖ No ACIP preference statement on brand

- MenACWY-TT (MenQuadfi™).
  - Licensed down to 9 months of age.
  - Studies: To get approval down to 6 months.

- Menveo™ (GSK) will still be available.
- 2 different vial formulations.
  - 2 vials-reconstitute, age 2mon-55yo (lyophilized).
  - 1 vial-no reconstitution, only approved for 10-55yo (liquid).
    - One vial and diluent together; decreases vaccine errors.

- MenQuadfi vs Menveo-immune non-inferiority based on seroresponse for all 4 serogroups.

Meningococcal Vaccines

- Reminders
  - MenQuadfi® and Menveo can be given regardless of DTaP.
  - MenACWY vaccines may be administered simultaneously with MenB vaccines if indicated, but at a different anatomic site, if feasible.
  - In children under 10 years needing a meningitis vaccine for travel, Menveo liquid is not appropriate for use.
  - Give vaccine at 11-12 y.o. then adolescent boosters at 16 y.o

RSV

- Monoclonal antibody injection (Nirsevimab) approved by CDC in August, expected availability in fall.
  - Will be covered by VFC.
- For neonates and infants born during or entering their first RSV season.
- Dosage is based on body weight:
  - <5 kg should be administered a 50 mg dose.
  - ≥5 kg should be administered a 100 mg dose.
- For children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season:
  - Single 200 mg dose administered as 2 IM injections.

- Children who have received Nirsevimab **should not** receive Palivizumab for the same RSV season.

RSV

- Timing
  - For infants born just before or during the RSV season (October – March): Administer 1 dose at birth or as soon as possible.
  - For infants born outside of the RSV season (April – September): Within the first months of the RSV season.
  - Administration can occur during birth hospitalization or in the outpatient setting.
- Coadministration
  - Simultaneous administration of Nirsevimab with age-appropriate vaccines is recommended.
- Provides passive immunization that extends through 5 months regardless of infant birth month

Products in the Pipeline

- COVID-19 (more in the next session)
  - Monovalent vaccine with an XBB.1.5-lineage of the Omicron variant
- Meningococcal (pentavalent)
  - In June, ACIP reviewed the potential uses of a new pentavalent meningococcal vaccine that would protect against serotypes A, B, C, W, & Y
- PCV20 is now available for ordering.

Schedule Changes

- Provider sites should have a process established for informing staff of any changes to ACIP recommendations.
  - Have 1 person in charge of tracking updates.
  - Have monthly trainings to review clinical guidance updates.

Illinois Coverage

ABLE. Estimated* coverage† with measles, mumps, and rubella; diphtheria, tetanus, and acellular pertussis; poliovirus; and varicella vaccines; grace period or provisional enrollment§; and any exemption¶,** among kindergartners, by immunization program — United States,†† 2021–22 school year

Immunization program	Kindergarten population§§	Surveyed,¶¶ %	2 Doses MMR,*** %	5 Doses DTaP,††† %	4 Doses polio,§§§ %	2 Doses VAR,¶¶¶ %	Grace period or provisional enrollment, %	Any exemption, %	Percentage point change in any exemption, 2020–2021
National estimate****	3,837,259	92.2	93.5	93.1	93.5	92.8	2.4	2.6	0.4
Median****	—	—	92.9	92.0	92.7	92.6	1.9	2.7	0.2
Illinois†††,§§§§	137,699	100.0	92.1	91.9	91.9	91.8	NR	≥1.7	NA

†††† The proportion surveyed is reported as 100% but might be <100% if based on incomplete information about the actual current enrollment.
§§§§ Philosophical exemptions were not allowed.

https://www.cdc.gov/mmwr/volumes/72/wr/mm7202a2.htm?s_cid=mm7202a2_w

Series Completion Coverage

- Recent study published in *Pediatrics* found that 17% of toddlers who started seven recommended vaccine series did not complete 1 or more:

  - **4 doses – diphtheria, tetanus, and acellular pertussis (DTaP).**
  - **4 doses – pneumococcal conjugate vaccine (PCV).**
  - **3 to 4 doses – haemophilus type b (Hib).**
  - 3 doses – hepatitis B (HepB).
  - 3 doses – polio (IPV).
  - 1 dose – measles, mumps, rubella (MMR).
  - 1 dose – varicella (VAR).

https://www.cdc.gov/mmwr/volumes/72/wr/mm7202a2.htm?s_cid=mm7202a2_w

Strategies for Increasing Uptake

- Simplify Scheduling:
  - Alert patients when vaccines are coming.
  - Self-scheduling through patient portal.
  - Automatically schedule return visits.
  - Site options – mass vaccination clinics, drive-thru vaccination, sites at local high school, or empty store fronts.

Strategies for Increasing Uptake

- Streamline Operations:
  - Pre-made vaccine card labels.
  - Only carry one vaccine manufacturer.

- Create a culture of vaccine confidence:
  - Staff townhalls so everyone stays up-to-date.
  - Empower vaccine champions.
  - Everyone in the office (clinical and non-clinical) should be trained on how to address patient concerns about vaccines.

Strategies for Increasing Uptake

- Celebrate Vaccination!
  - Show off “I’m vaccinated!” stickers, pins, or posters.
  - Marketing materials in waiting rooms and social media.
  - Offer/talk about vaccinations at every visit.
  - For hesitant people – treat it as an ongoing conversation.

SESSION 3:
COVID-19 VACCINES

Learning Objectives:

After this session participants will be able to

1

Summarize current data of COVID-19 vaccination rates.

2

Outline storage and expiration date information for each vaccine manufacturer.

3

Describe current COVID-19 vaccine administration guidelines.

Current Vaccination Rates

People with an Updated (Bivalent) Booster Dose‡	Count	Percent of U.S. Population
Total	56,478,510	17.0%
Population ≥ 5 Years of Age	56,352,709	18.0%
Population ≥ 12 Years of Age	54,974,636	19.4%
Population ≥ 18 Years of Age	52,996,306	20.5%
Population ≥ 65 Years of Age	23,699,191	43.3%

*Vaccination coverage reporting is no longer required as of May 2023
Data as of 5/10/23

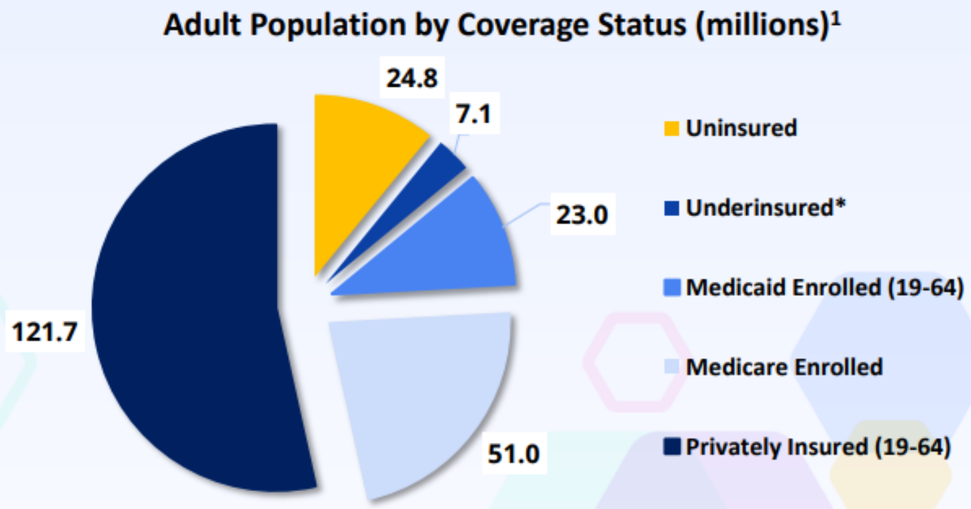
Commercialization

- Commercialization – the transition from direct government purchase to purchase by public and private consumers.
- There might be upfront costs for providers who provide COVID-19 vaccines.
  - Moderna: $130/dose.
  - Pfizer: $110-$130/dose.
- The AAP is advocating for:
  - Longer invoice and payment schedules so that pediatricians can be reimbursed before having to purchase additional vaccines.
  - Simplified and improved labeling of COVID-19 vials to minimize errors in administration.
  - An easier return process for expired doses.
  - Single doses vials for all products.

Bridge Access Program

Why Do We Need the Bridge Access Program for COVID-19 Vaccines?

There are **25-30 million adults (ages 18-64) without insurance,** and additional adults whose insurance will not provide no-cost coverage for COVID-19 vaccines after these products are commercialized



This program will serve as **temporary bridge to the permanent and comprehensive Vaccines for Adults Program** proposed in the FY23 and FY24 President's Budgets

*Underinsured is defined here as related to vaccination coverage.
1. Data are internal CDC estimates.

Commercialization Cont.

- HHS Commercialization Transition Guide: Sunsetting the US Government COVID-19 Vaccine Distribution Program.
  - Issued July 6, 2023

- Access: VFC program, Bridge Access Program for adults without insurance, coverage by private insurance.
  - Private insurance will cover the 2023 – 2024 COVID-19 vaccine immediately - Section 3203 of the CARES Act expedites coverage of COVID-19 vaccines
  - COVID-19 vaccines will be covered under Medicare Part B without cost-sharing – Inflation Reduction Act from August 2022 includes key provisions.

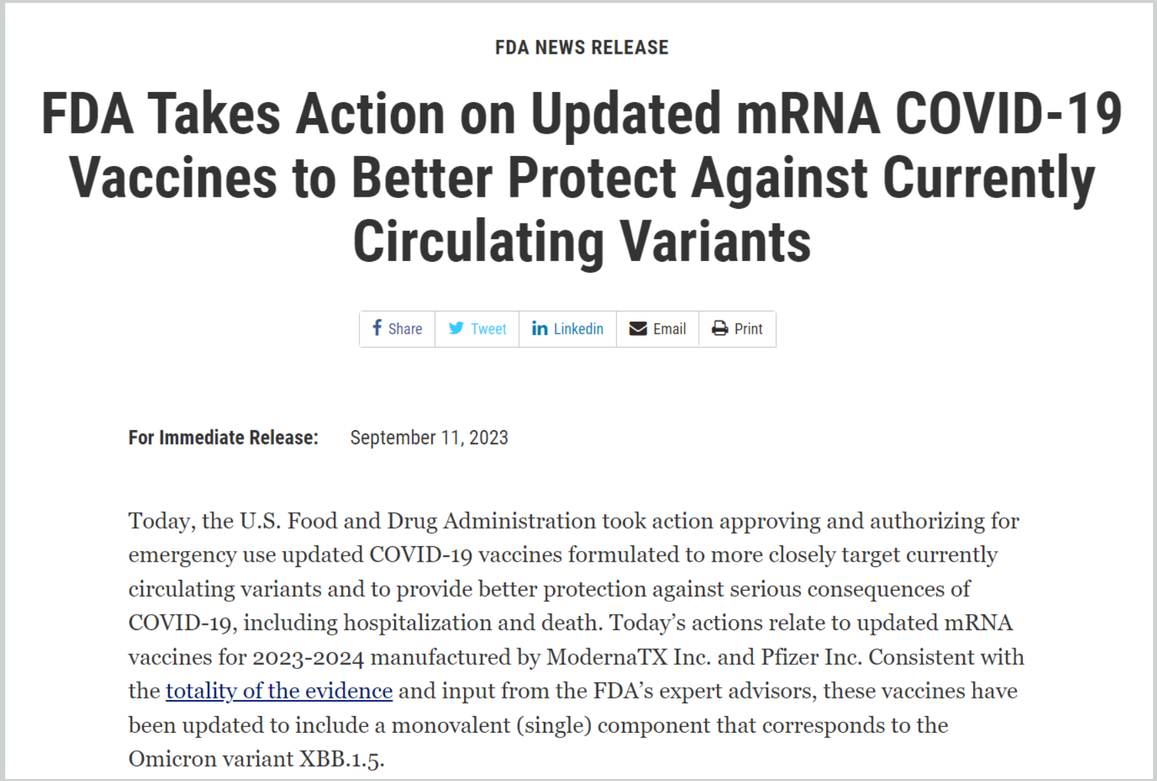
- Ordering:
  - VFC & Private Stock: ordered through the same process as other commercial vaccines
  - Bridge Access: separate ordering process.

Fall 2023 Vaccines

- Updating COVID-19 vaccines to XBB.1.5 strain: FDA recommendation 7/15/2023.
- Going back to a monovalent formula.
- Why?
  - WHO is not seeing any evidence that the earliest variant is still circulating.
  - We can drop that from the formula.
  - Including it could hurt as we keep teaching our immune system to recognize the old version of the virus rather than the new one.
- Novavax and Moderna found that a monovalent vaccine may be more advantageous to mice's immune systems than a bivalent vaccine.

https://www.fda.gov/vaccines-blood-biologics/updated-covid-19-vaccines-use-united-states-beginning-fall-2023#:~:text=For%20the%202023%2D2024%20formulation,lineage%20of%20the%20Omicron%20variant.

2023 – 2024 Products



FDA NEWS RELEASE

FDA Takes Action on Updated mRNA COVID-19 Vaccines to Better Protect Against Currently Circulating Variants

Share Tweet Linkedin Email Print

For Immediate Release: September 11, 2023

Today, the U.S. Food and Drug Administration took action approving and authorizing for emergency use updated COVID-19 vaccines formulated to more closely target currently circulating variants and to provide better protection against serious consequences of COVID-19, including hospitalization and death. Today's actions relate to updated mRNA vaccines for 2023-2024 manufactured by ModernaTX Inc. and Pfizer Inc. Consistent with the totality of the evidence and input from the FDA's expert advisors, these vaccines have been updated to include a monovalent (single) component that corresponds to the Omicron variant XBB.1.5.

News Release

On September 11, 2023, the FDA…

- Approved the supplemental Biologics License Application for
  - COMIRNATY or Pfizer and SPIKEVAX or Moderna's mRNA COVID-19 vaccine for those ages 12+
- Gave emergency use authorization (EUA) for
  - Pfizer-BioNTech and Moderna's COVID-19 Vaccine (2023-2024 Formula) for those 6 months through 11 years of age.

2023 – 2024 Products

CDC Recommends Updated COVID-19 Vaccine for Fall/Winter Virus Season

Print

Press Release

For Immediate Release: Tuesday, September 12, 2023
Contact: Media Relations
(404) 639-3286

CDC recommends everyone 6 months and older get an updated COVID-19 vaccine to protect against the potentially serious outcomes of COVID-19 illness this fall and winter. Updated COVID-19 vaccines from Pfizer-BioNTech and Moderna will be available later this week.

News Release

On September 12, 2023, CDC's Advisory Committee on Immunization Practices (ACIP) met and voted in favor recommending the 2023 – 2024 COVID-19 vaccine formulation for everyone 6 months and older.

The CDC also adopted this recommendation.

Deauthorized Vaccines

- Bivalent Moderna and Pfizer-BioNTech COVID-19 vaccines are no longer authorized for use in the United States.

- Per IDPH SIREN (9/13/23): Medical waste disposal requirements are set by state or local environmental agencies and may vary by jurisdiction.
  - Remove the current mRNA vaccines from your physical inventory immediately and dispose in compliance with vaccine disposal regulations.\

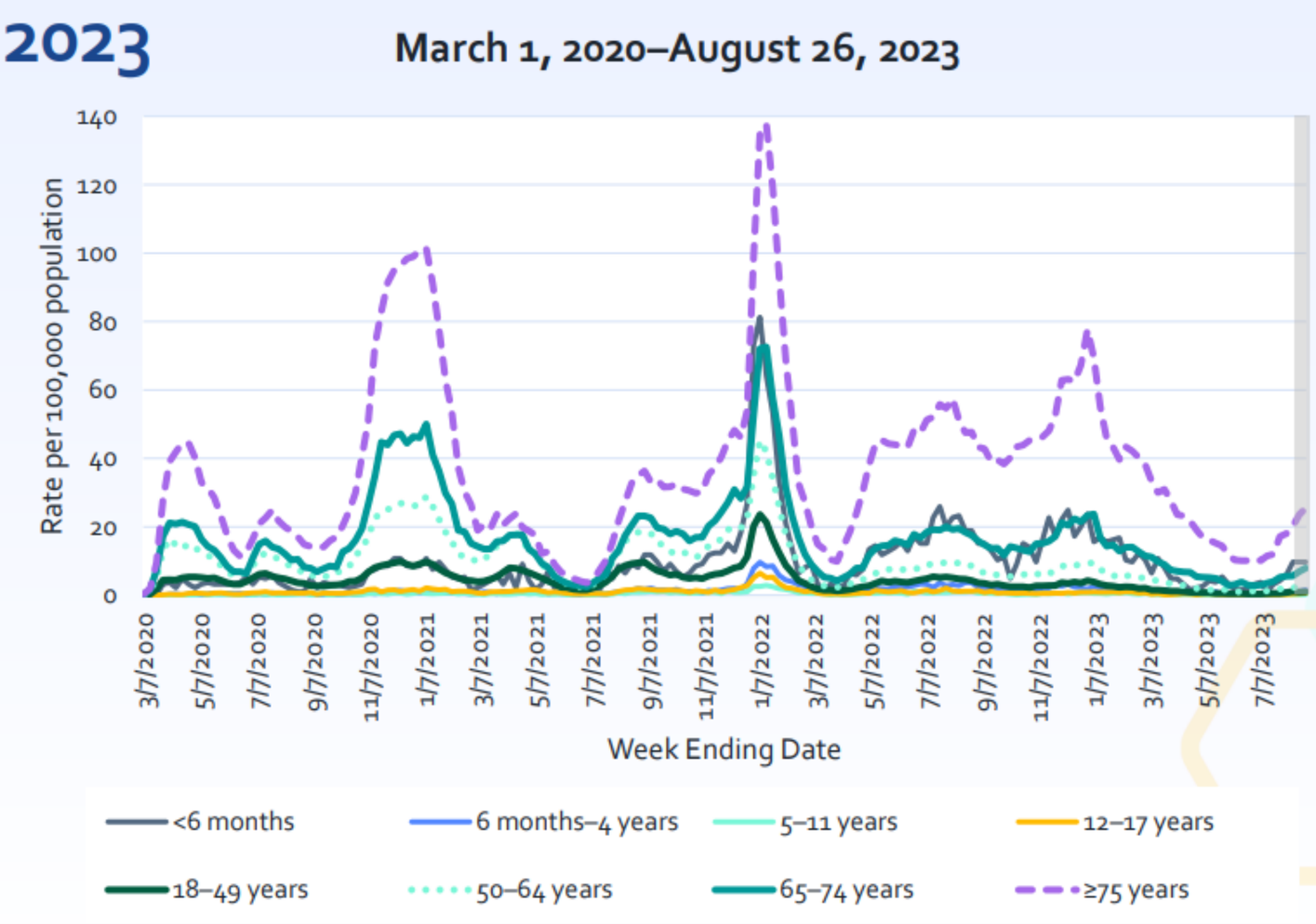
- The original Novavax COVID-19 vaccine remains authorized for use as a 2-dose primary series for those ages 12+ and as a booster dose for those ages 18+ in limited situations.
  - Authorizations or approvals for 2023 – 2024 Novavax COVID-19 vaccine will be determined by FDA with CDC recommendations to follow.

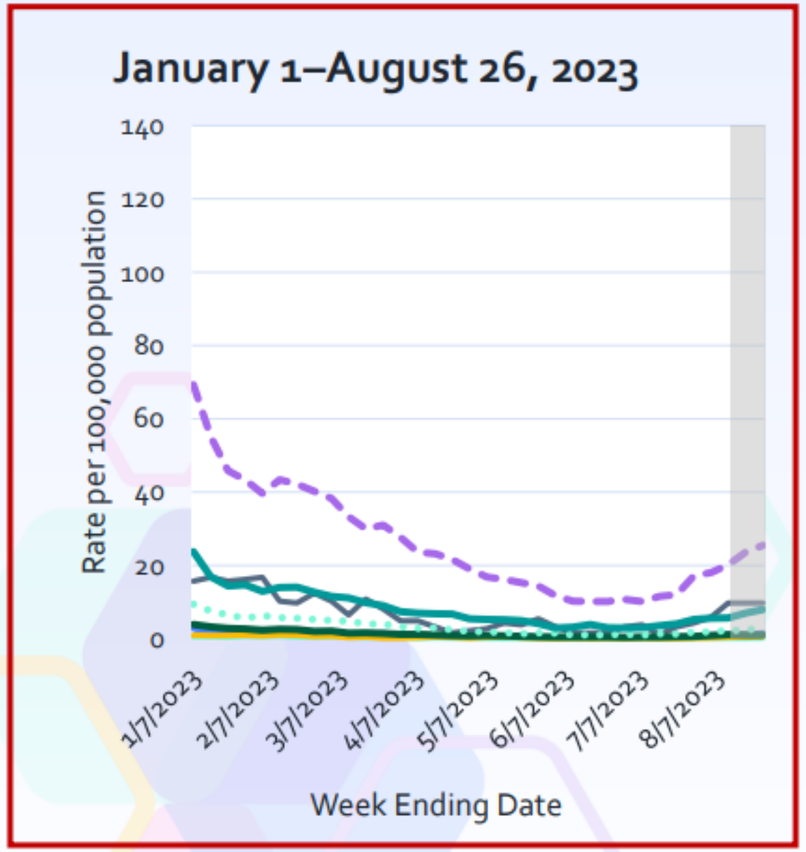
Current landscape of SARS-CoV-2

- More than 90% of currently circulating viruses are XBB lineage viruses with 1-2 additional substitutions in RBD in comparison to XBB.1.5
- BA.2.86 is a newly detected lineage with > 30 amino acid substitutions in spike
  - Thus far, the number of viruses detected is still low
  - Sequence numbers are too low to calculate proportion (<0.05%)
- Preliminary pseudovirus neutralization data generated by multiple labs do not indicate a large reduction in neutralizing activity against BA.2.86
- CDC has generated a BA.2.86 isolate, is currently working on titrations before neutralization and has begun distribution to external laboratories for further examination

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-09-12/02-COVID-Thornburg-508.pdf

Weekly Population-Based Rates of COVID-19-Associated Hospitalizations — COVID-NET, March 2020–August 26, 2023

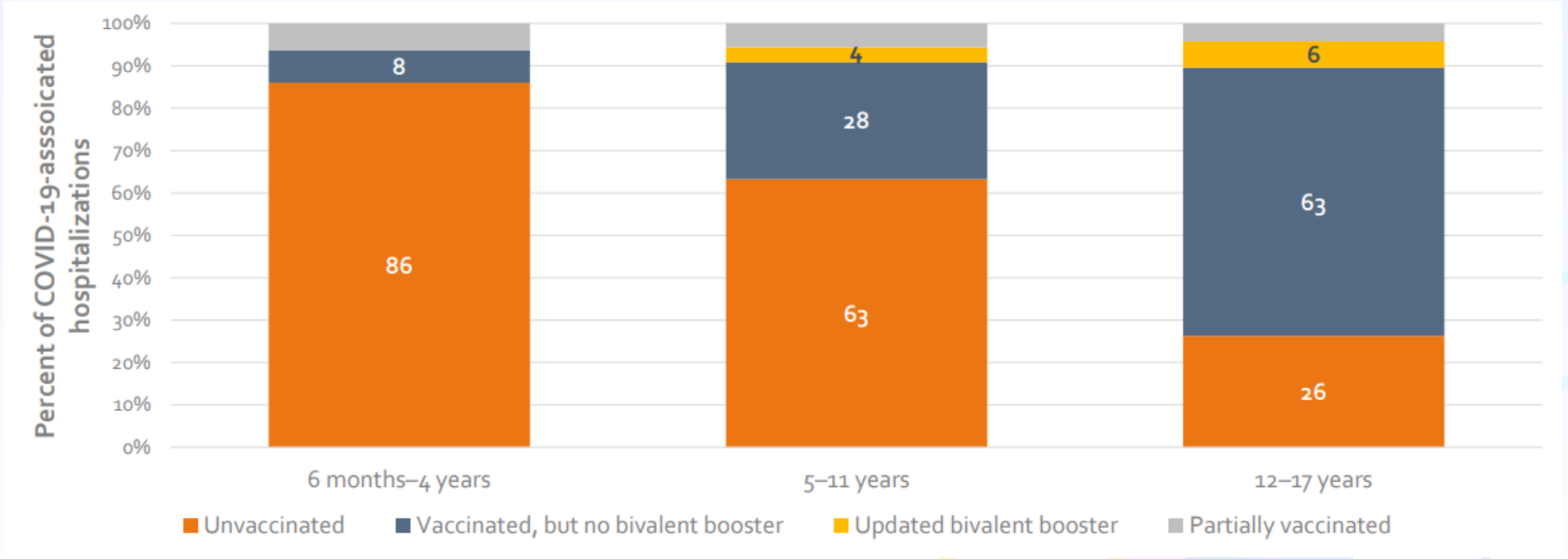




Rates highest in ≥75 years, followed by infants <6 months and adults 65–74 years

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-09-12/03-COVID-Havers-508.pdf

Vaccination Status by Age Group among Infants, Children and Adolescents Ages ≤17 Years Hospitalized for COVID-19 — COVID-NET, January–June 2023



Data are limited to hospitalizations where COVID-19 is a likely primary reason for admission. ***Unvaccinated****: No recorded doses of COVID-19 vaccine.* ***Vaccinated, but no bivalent booster****: Completed a primary series with or without ≥1 booster dose but did not receive an updated bivalent booster dose.* ***Updated bivalent booster****: Received updated bivalent booster dose.* ***Partially vaccinated****: Received at least one dose of COVID-19 but was not considered fully vaccinated at the time of a positive SARS-CoV-2 test. Persons with unknown vaccination status are excluded.*

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-09-12/03-COVID-Havers-508.pdf

Pediatric vaccine preventable diseases: Deaths per year in the United States prior to recommended vaccines compared to COVID-19

	Hepatitis A[1]	Meningococcal (ACWY)[2]	Varicella[3]	Rubella[4]	Rotavirus[5]	COVID-19[6]
Age	<20 years	11–18 years	5–9 years	All ages	<5 years	6 months–<18 years
Time period	1990–1995	2000–2004	1990–1994	1966–1968	1985–1991	2022
Average deaths per year	3	8	16	17	20	≤1 year: 156 1–4 years: 101 5–19 years:292

[1]Vogt TM , Wise ME, Bell BP, Finelli L. Declining hepatitis A mortality in the United States during the era of hepatitis A vaccination. J Infect Dis2008; 197:1282–8.
[2]National Notifiable Diseases Surveillance System with additional serogroup and outcome data from Enhanced Meningococcal Disease Surveillance for 2015-2019.
[3]Meyer PA, Seward JF, Jumaan AO, Wharton M. Varicella mortality: trends before vaccine licensure in the United States, 1970-1994. J Infect Dis. 2000;182(2):383-390. doi:10.1086/315714
[4]Roush SW , Murphy TV; Historical comparisons of morbidity and mortality for vaccine-preventable diseases in the United States. JAMA 2007; 298:2155–63.
[5] Glass RI, Kilgore PE, Holman RC, et al. The epidemiology of rotavirus diarrhea in the United States: surveillance and estimates of disease burden. J Infect Dis. 1996 Sep;174 Suppl 1:S5-11
[6] http://wonder.cdc.gov/mcd-icd10-provisional.html on Aug 1, 2023 . COVID vaccine first introduced in 12-17 years in May 2021; in 5-11 years in November 2021 and in 6 months – 4 years in June 2022

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-09-12/11-COVID-Wallace-508.pdf

Summary

Benefits and Harms

- Monovalent XBB containing COVID-19 vaccines **increase the immune response** against the currently circulating variants
- Last year's updated vaccine was **effective** at preventing medically attended COVID-19, hospitalization due to COVID-19, and death due to COVID-19
- Accumulating evidence that COVID-19 vaccination reduces Post-COVID Conditions among both children and adults
- COVID-19 vaccines have a **high degree** of safety
  - Rare events of myocarditis and anaphylaxis have been seen in post-authorization studies
  - Unlikely that updating the formulation would increase adverse event rates
- **Benefits** are anticipated in all age groups; benefits of COVID-19 vaccines vary by **age** and incidence of COVID-19 hospitalizations
- **Benefits outweigh risks** in age groups for which risk of myocarditis is highest
- Modeling projects **more hospitalizations and deaths averted** when updated doses are **universally recommended** compared to no recommendation or recommended only for persons ≥65 years

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-09-12/11-COVID-Wallace-508.pdf

Expected Ordering

Expected

XBB.1.5 ordering
subject to change

2023–2024 COVID-19 VACCINE ORDERING

Monovalent XBB.1.5 *Last updated September 13, 2023. Information is subject to change.*

I-VAC ILLINOIS VACCINATES AGAINST COVID-19
A project led by the Illinois Chapter of the American Academy of Pediatrics

FORMULATION	CPT CODE	PRESENTATION	MINIMUM ORDER QTY	HOW TO ORDER	COST	DELIVERY TIME
Novavax						
Patient age 12 years and older	91304	Multi-dose vials containing 5 doses	50 doses	• Through VFC and other state programs • Wholesaler/distribution channels	Unknown - Prices will depend on the contract or group affiliation	Varies
Pfizer						
Patient age 6 months–4 years	91318	Multi-dose vials containing 3 doses	30 doses	• Through VFC and other state programs • Pfizer Prime: 15% of an order that is received can be returned • Wholesaler/distribution channels	Unknown - Prices will depend on the contract or group affiliation	Varies
Patient age 5 years–11 years	91319	Single-dose vials	10 doses			
Patient age 12 years and older	91320	Single-dose vials or single-dose prefilled syringes*				
Moderna						
Patient age 6 months–11 years	91321	Single-dose vials that come in 10-count cartons	10 doses	• Through VFC and other state programs • Moderna Direct: 10% of an order that is received can be returned • Wholesaler/distribution channels	Unknown - Prices will depend on the contract or group affiliation	Varies, Moderna would begin shipping the vaccines after FDA approval
Patient age 12 years and older	91322	Single-dose prefilled syringes sold in 10-count cartons with a blister pack option				

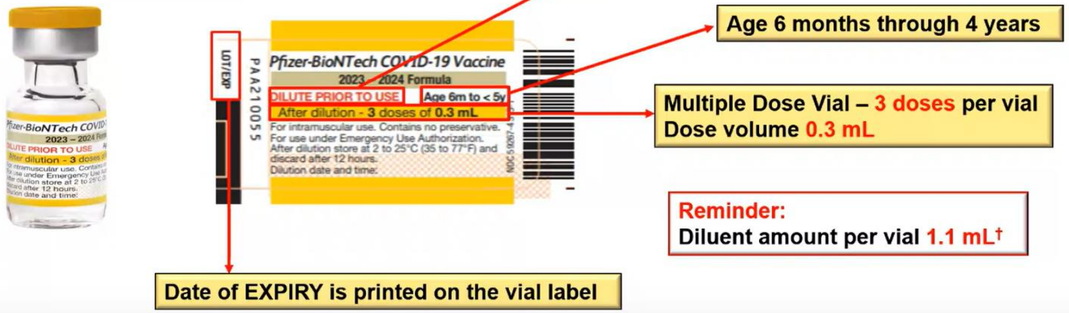
*There will be limited quantities of prefilled syringes and they will not be available for initial stocking orders.

Sources: www.pfizer.com/news/announcements/pfizer-and-biontech-submit-applications-us-fda-omicron-xbb15-adapted-monovalent
https://publications.aap.org/aapnews/news/25384?autologincheck=redirected

2023 – 2024 Packaging: Pfizer

Pfizer: 6 months – 4 years vaccine has a yellow cap and yellow label.

Pfizer-BioNTech COVID-19 Vaccine, 2023-2024 Formula
Ages 6 months through 4 years
Multiple Dose Vials

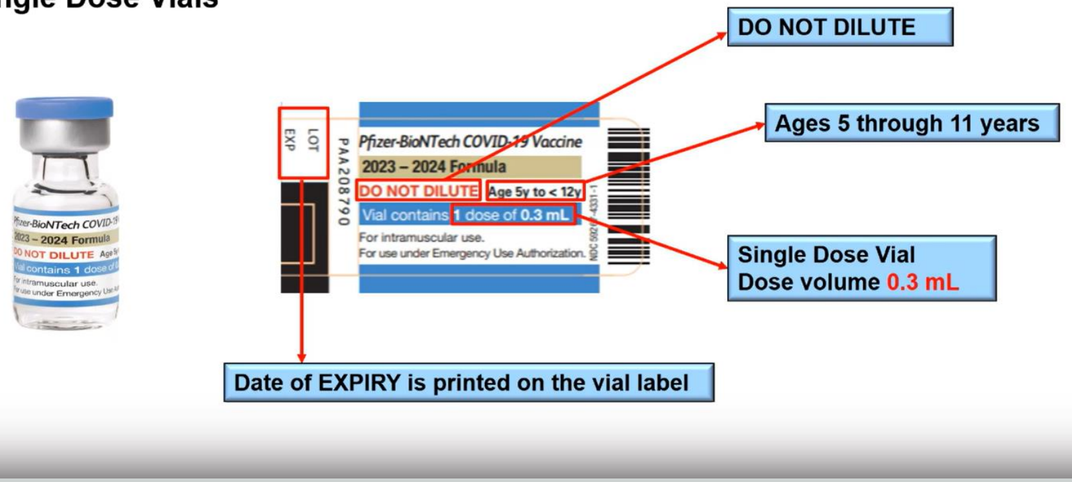


†*Diluent: sterile 0.9% Sodium Chloride Injection, USP. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.*

Pfizer: 5-11 vaccine has a blue cap and blue label.

ALL INFORMATION ON THIS SLIDE IS PRELIMINARY – SUBJECT TO CHANGE PENDING REGULATORY AUTHORIZATION/APPROVAL

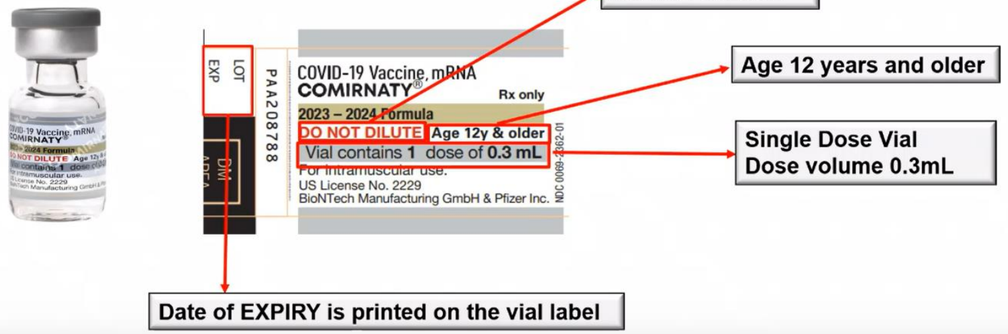
Pfizer-BioNTech COVID-19 Vaccine, 2023-2024 Formula
Ages 5 through 11 years
Single Dose Vials



2023 – 2024 Packaging: Pfizer

Pfizer: 12+ vaccine has a gray cap and gray label.

COMIRNATY® (COVID-19 Vaccine, mRNA) 2023-2024 Formula
Ages 12 years and older
Single Dose Vials



Pfizer: 12+ prefilled syringes

COMIRNATY® (COVID-19 Vaccine, mRNA) 2023-2024 Formula
Ages 12 years and older
Prefilled Syringes*

Important Considerations for Prefilled Syringes

Dose: 30 mcg/0.3 mL

Storage During Use:**

- After thawing:
  - If thawed in the **carton**, syringes can be stored:
    - Refrigerator (2-8°C) 10 weeks
    - Room temperature (8-25°C): 12 hours prior to use
  - If **individual frozen syringes** are thawed at **room temperature** (i.e. outside of the carton), they must be used **within 4 hours of thawing**

After opening the tip cap and attaching an appropriate needle, the prefilled syringe should be used **immediately**.

- If it cannot be used immediately, it must be used within **4 hours**

2023 – 2024 Packaging: Moderna

Moderna: Vaccine for ages 6 months – 11 years has a dark blue cap and a green label border.

Moderna: Vaccine for ages 12 years and older has a blue cap and a blue label border.

2023–2024 COVID-19 VACCINE

Monovalent XBB.1.5 *Last updated September 15, 2023*

I-VAC ILLINOIS VACCINATES AGAINST COVID-19
A project led by the Illinois Chapter of the American Academy of Pediatrics

	MODERNA		PFIZER			
AGE INDICATIONS AND FORMULATION	6 Months–11 Years	12+ Years	6 Months–4 Years	5–11 Years	12+ Years	12+ Years Prefilled Syringe
VIAL CAP COLOR	Dark Blue	Dark Blue	Yellow	Blue	Gray	N/A
VIAL LABEL BORDER COLOR	Green	Dark Blue	Yellow	Blue	Gray	N/A
PREPARATION	Do Not Dilute	Do Not Dilute	Dilute	Do Not Dilute	Do Not Dilute	N/A
DOSE	25 mcg/0.25 mL dosage	50 mcg/0.5 mL dosage	3 mcg/0.3 mL dosage	10 mcg/0.3 mL dosage	30 mcg/0.3 mL dosage	30 mcg/0.3 mL dosage
DOSES PER VIAL	1	1 – Single-dose Vial or Prefilled Syringe	3	1	1	1 – Prefilled Syringe
ULT FREEZER (-90°C TO -60°C)	DO NOT STORE	DO NOT STORE	12 Months	12 Months	18 Months	9 Months
FREEZER (-50°C TO -15°C)	Until Expiration	Until Expiration	DO NOT STORE	DO NOT STORE	DO NOT STORE	DO NOT STORE
REFRIGERATOR (2°C TO 8°C)	30 Days	30 Days	10 Weeks	10 Weeks	10 Weeks	10 Weeks
ROOM TEMPERATURE (8°C TO 25°C)	24 Hours	24 Hours	12 Hours Prior to First Puncture	12 Hours Prior to Use	12 Hours Prior to Use	4–12 Hours*
AFTER FIRST PUNCTURE (2°C TO 25°C)	N/A	12 Hours or Discard After Single Use	Discard After 12 Hours	N/A	N/A	N/A
THAW TIME	In Refrigerator: 45 mins At Room Temp: 15 mins	**Single-Dose Vial:** In Refrigerator: 45 mins At Room Temp: 15 mins **Prefilled Syringe:** In Refrigerator: 1 hour At Room Temp: 45 mins	In Refrigerator: Up to 2 hours At Room Temp: 30 mins	In Refrigerator: Up to 2 hours At Room Temp: 30 mins	In Refrigerator: Up to 2 hours At Room Temp: 30 mins	**Thawed in carton:** In Refrigerator: Up to 2 hours At Room Temp: 60 mins

*Thawed in carton: 12 hours prior to use. Thawed outside of carton: Use within 4 hours of thawing.

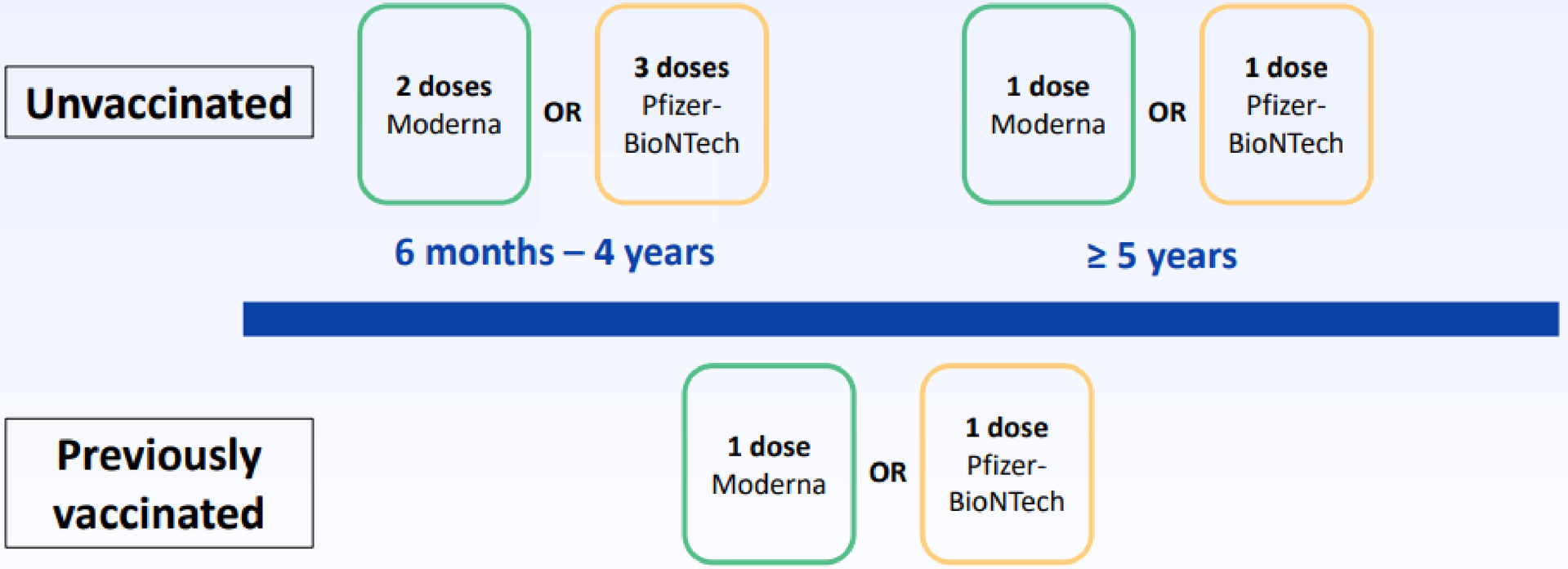
Moderna Carton Dimensions– XBB.1.5

TYPE	DESCRIPTION	ITEM AND PACKING INFORMATION					
			Weight (lbs)	Depth (in)	Width (in)	Height (in)	Volume (in^3)
Prefilled Syringe Blister Pack	• 0.5 mL single-dose prefilled syringe • 10-count carton (blister pack) • 12+ years of age	Carton	0.24 lbs	2.25 in	5.25 in	3.43 in	38.84 in^3
		ITEM AND PACKING INFORMATION					
Prefilled Syringe	• 0.5 mL single-dose prefilled syringe • 10-count carton • 12+ years of age		Weight (lbs)	Depth (in)	Width (in)	Height (in)	Volume (in^3)
		Carton	0.20 lbs	4.10 in	4.14 in	1.42 in	24.10 in^3
		ITEM AND PACKING INFORMATION					
Single-Dose Vial	• 0.5 mL single-dose vial • 10-count carton • 12+ years of age		Weight (lbs)	Depth (in)	Width (in)	Height (in)	Volume (in^3)
		Carton	0.21 lbs	3.68 in	1.54 in	2.20 in	11.76 in^3

in = inches; lbs = pounds. Note that gross weight is under evaluation.

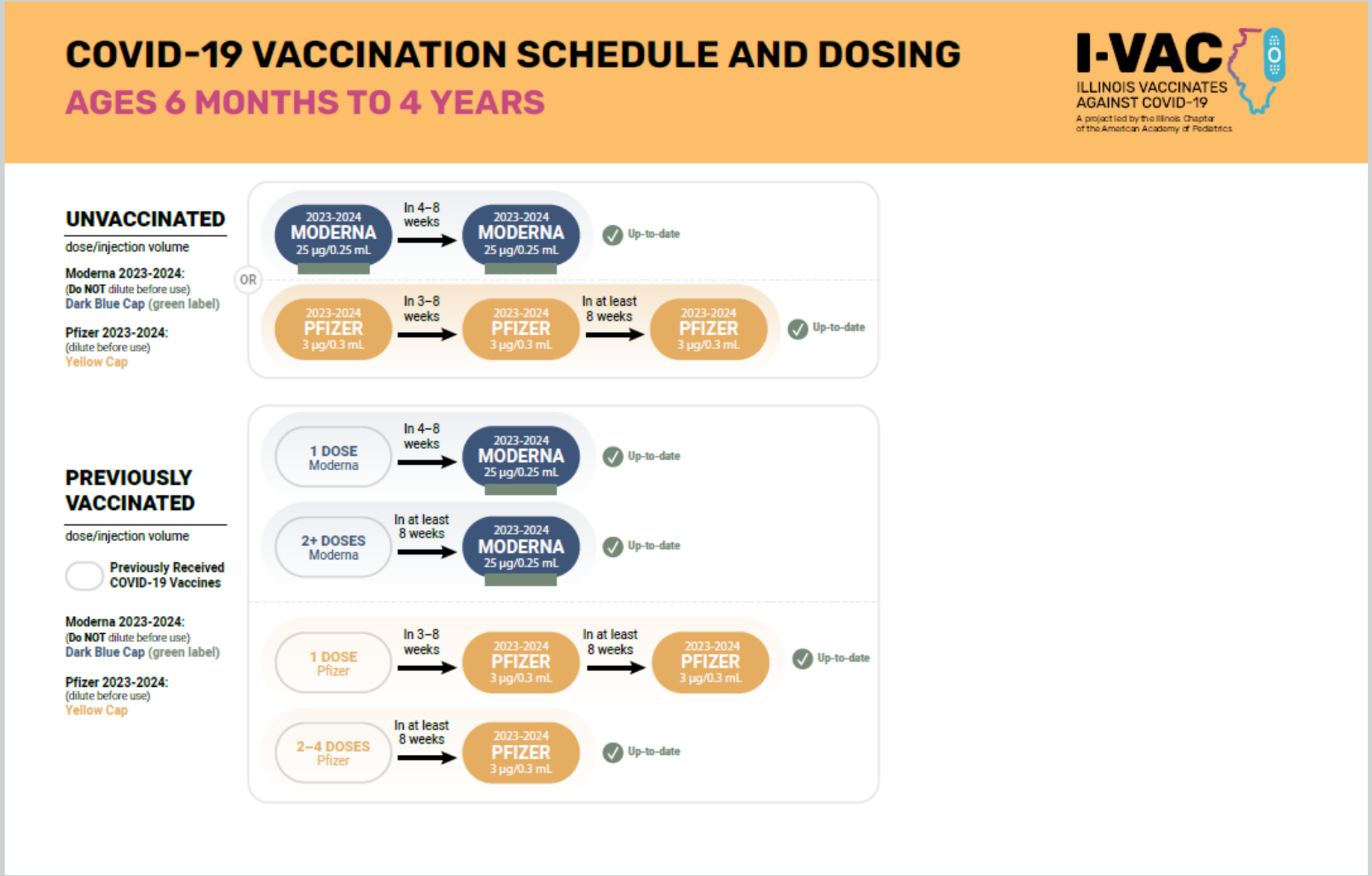
Dosing and Administration

Proposed 2023 – 2024 COVID-19 vaccine recommendations for mRNA COVID-19 vaccines

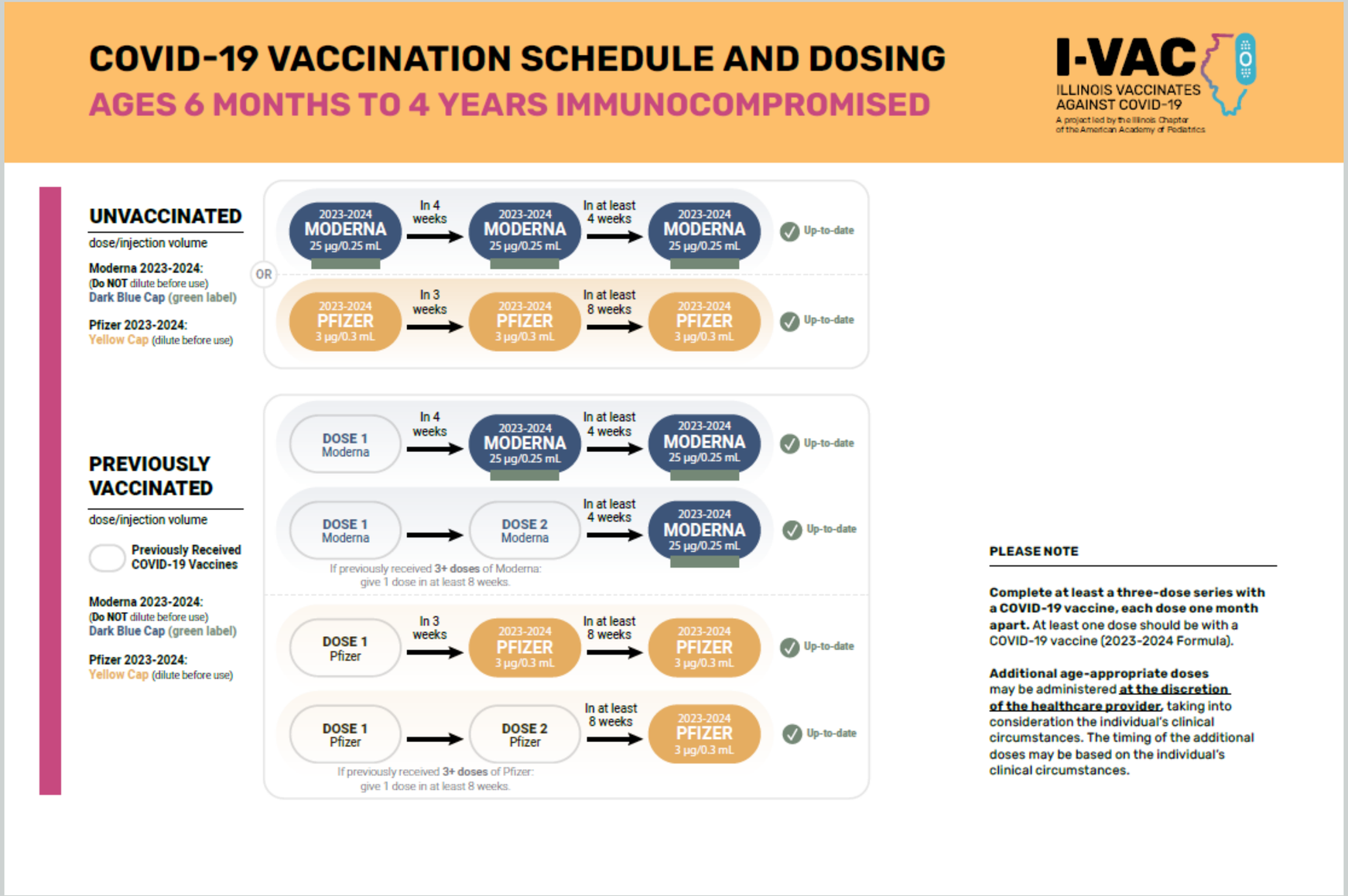


Note: Those ages 6 months – 4 years who have previously received a single dose of Pfizer-BioNTech would need 2 additional doses. Additional doses are recommended for persons with immunocompromising conditions.

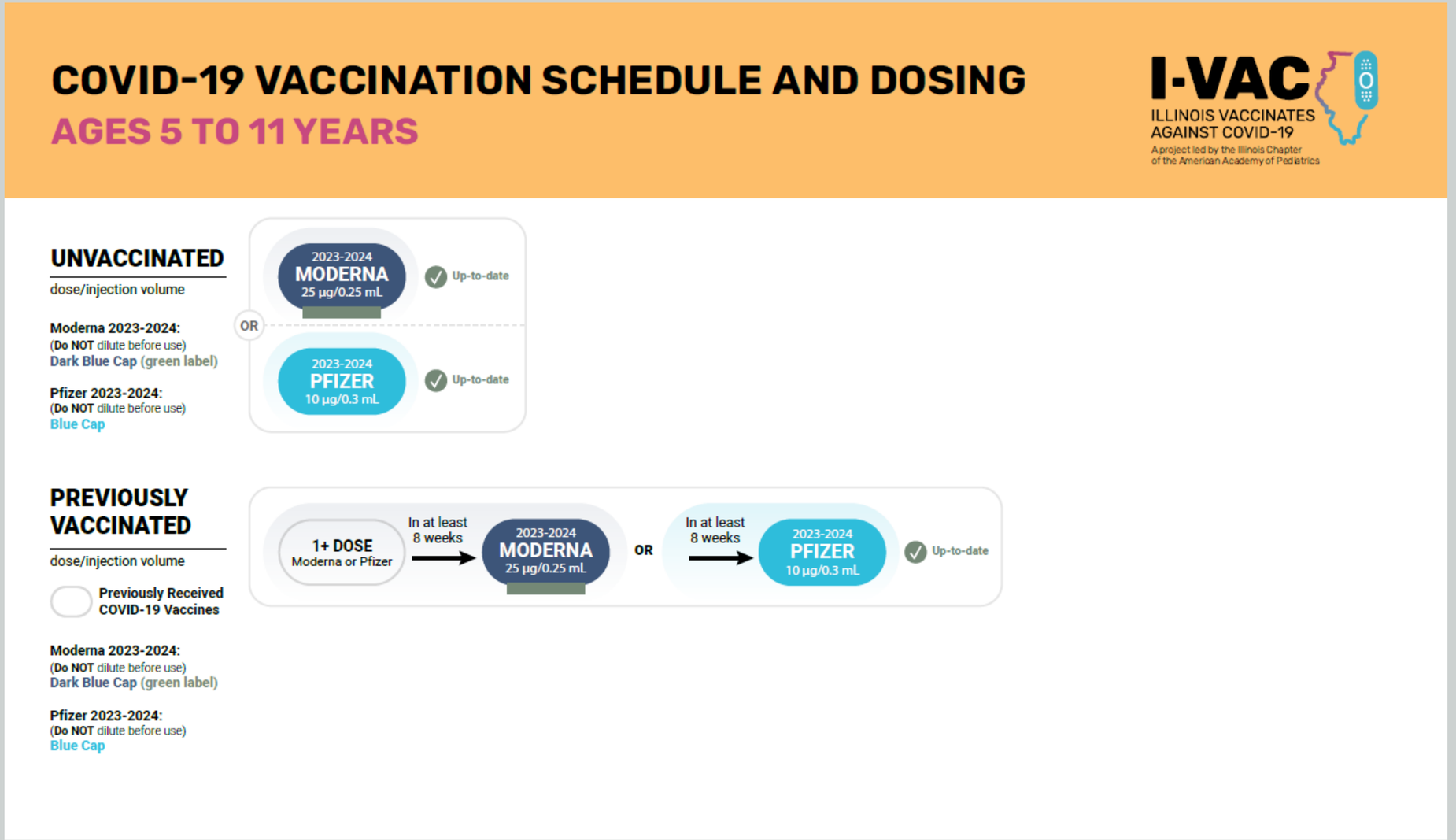
Dosing and Administration



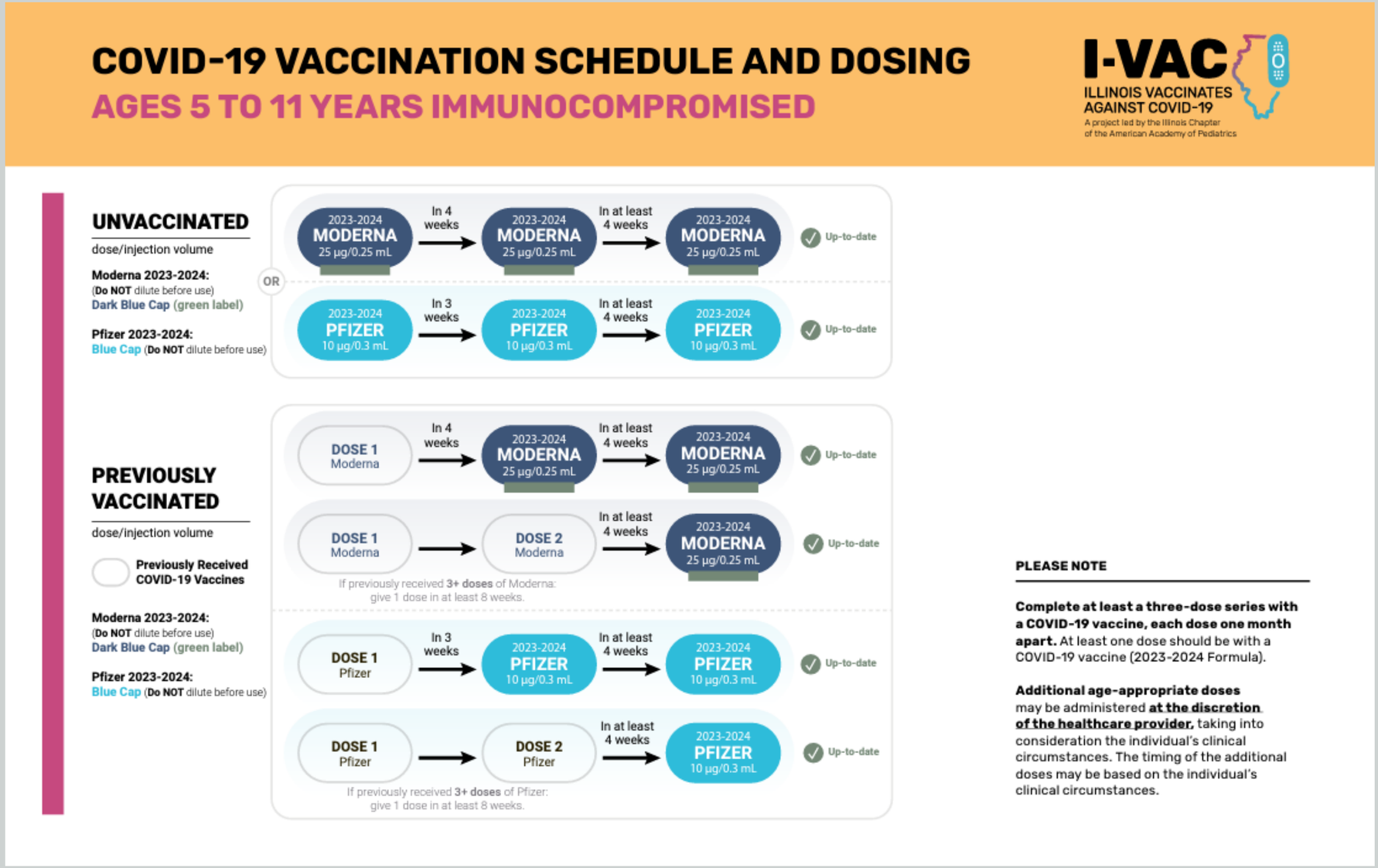
Dosing and Administration



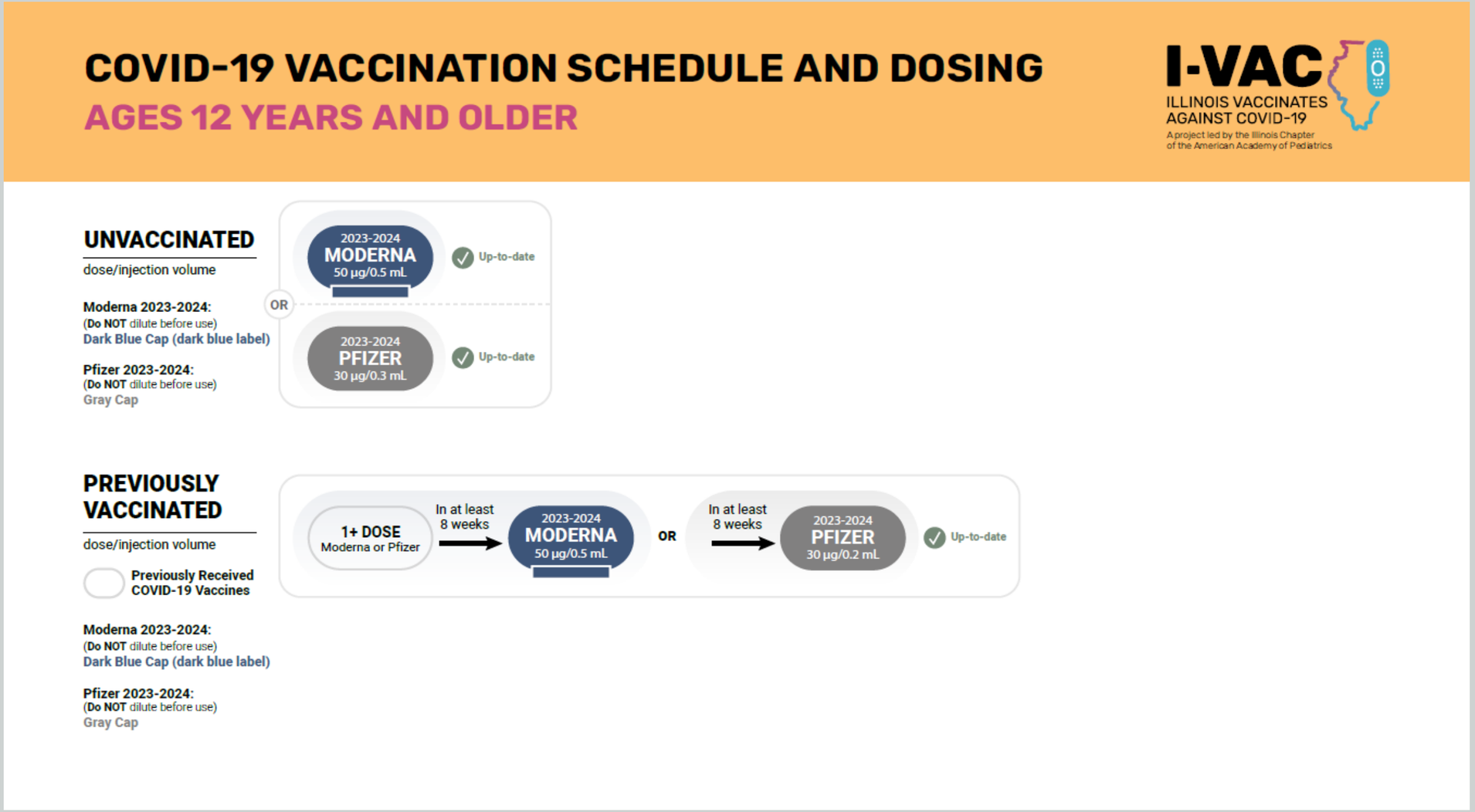
Dosing and Administration



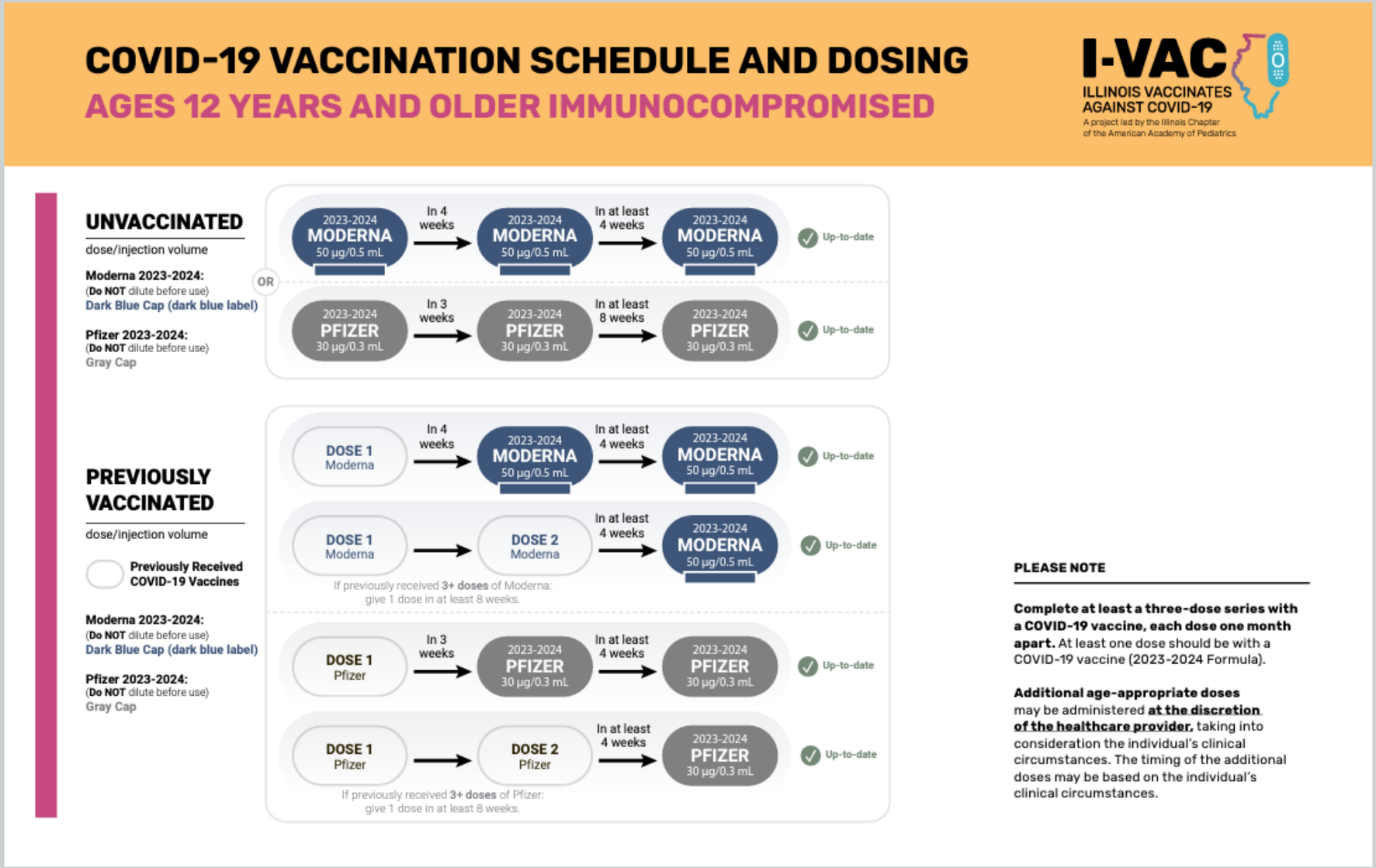
Dosing and Administration



Dosing and Administration



Dosing and Administration



Expiration Dates

Manufacturer	How to find it
Moderna (Spikevax)	• Scan QR code on the vial or carton. • Website: Look up tool.
Pfizer	• Website: Look up tool . • See EUA fact sheets for providers.
Novavax	• Scan QR code on outer carton. • Website: Look up tool.

Reporting to VAERS

Required by law to report the following to VAERS:

1. Vaccine administration errors, whether or not associated with an adverse event (AE)
    - If the incorrect mRNA COVID-19 vaccine product was inadvertently administered for a second dose in a 2-dose series, VAERS reporting is required.

2. Cases of myocarditis after a Pfizer-BioNTech, Moderna, or Novavax vaccine.

3. Cases of pericarditis after a Pfizer-BioNTech, Moderna, or Novavax vaccine.

VAERS reporting is not required for:

- Mixed series is given intentionally (e.g., due to hypersensitivity to a vaccine ingredient).

https://www.cdc.gov/vaccinesafety/hcproviders/reportingadverseevents.html

Reporting to VAERS

4. Serious AEs regardless of whether the reporter thinks the vaccine caused the AE:
    - Death
    - A life-threatening AE
    - Inpatient hospitalization or prolongation of existing hospitalization
    - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
    - A congenital anomaly/birth defect
    - An important medical event that based on appropriate medical judgement may require medical or surgical intervention to prevent one of the outcomes listed above
5. Cases of Multisystem Inflammatory Syndrome in adults or children.
6. Cases of COVID-19 that result in hospitalization or death.

Report to VAERS any clinically significant AEs following vaccination, even if you are not sure whether the vaccine caused the event.

https://vaers.hhs.gov/reportevent.html

Reporting to VAERS

- Fill out a separate form for each patient.
- List any medicines, supplements, and remedies the patient is taking or using.
- List any allergies.
- List acute illnesses and chronic conditions the patient may have.
- Fill out the information of the person filling out the form and contact information of the provider to contact, correctly and completely.
- Call 1-800-822-7967 or email info@vaers.org for help or information .

Combating Hesitancy and Misinformation

- Misinformation vs. disinformation
  - When people spread misinformation, they often believe what they are sharing
  - Disinformation is intended to mislead others.

- Address hesitancy and misinformation by increasing vaccine confidence:
  - Create vaccine champions of your staff
  - Help simplify scheduling for patients and alert them when vaccines are available.
  - Streamline operations for your staff.
  - Be empathetic, compassionate, and sensitive to culture, family dynamics, and circumstances that may influence how patients view vaccines.

- Motivational interviewing is an evidence-based and culturally sensitive way of speaking with unvaccinated patients about getting vaccinated.

Discussion

- Case scenario: You are carrying both the Moderna and Pfizer products for all ages at your clinic. What are some ways you can minimize vaccine administration errors?
- 5 minutes to discuss different strategies at your tables.
- What are some ways you minimize vaccine administration errors in your own practice?
- 5 minutes to present one strategy to the group.

Lunch

Please return by 12:35

SESSION 4:
OTHER TOPICS

Learning Objectives:

After this session participants will be able to

1

Describe vaccine hesitancy, misinformation, and disinformation.

2

Demonstrate strategies for combatting vaccine misinformation and disinformation.

3

Outline ways to discuss vaccine hesitancy with patients.

Unfortunate Theme

- 23 million children missed out on basic childhood vaccines through routine health services in 2020.
  - The highest number since 2009 and 3.7 million more than in 2019.

- Children were on track to miss an estimated 9 million vaccination doses in 2020, a decrease of up to 26% in childhood vaccination doses compared to 2019.

Unfortunate Theme

Vaccination	BCBS 2020 estimated vax rate	BCBS % decrease from 2019	CDC herd immunity thresholds	BCBS 2020 est. vax rate vs herd immunity thresholds
Measles	88.2%	-26%	94%	-4.8
Pertussis	79.3%	-26%	92%	-12.7
Polio	88.9%	-16%	86%	+2.9

The Blue Cross Blue Shield Association Reports Steep Decline in Childhood Vaccinations Due to COVID-19 Pandemic, Putting Community Protection at Risk | Blue Cross Blue Shield (bcbs.com)

Unfortunate Theme

- Vaccination coverage among kindergartners nationwide:
  - Lower during the 2020-21 school year compared with 2019–20 school year (95% to ~94%).
  - Lower during the 2021-22 school year compared with the 2020-21 school year (~94% to ~93% for all state-required vaccines).
- Non-exempt, undervaccinated students often attend school while in a grace period or are provisionally enrolled.
- In many states, exemption policies were expanded either formally or informally during the 2020– 21 school year.

https://www.cdc.gov/mmwr/volumes/72/wr/mm7202a2.htm?s_cid=mm7202a2_w

https://www.cdc.gov/mmwr/volumes/71/wr/mm7116a1.htm

Importance of Influenza, COVID-19 & Routine Vaccines

Since we do not have vaccines to protect against every disease, it is even more important to use the vaccines that we do have to keep children out of the hospital.

Preliminary interim estimates—NVSN

- Through January 25, 2023, influenza vaccination significantly reduced laboratory confirmed medically attended influenza
  - 68% (95% CI: 46, 81) against pediatric hospitalizations
  - 42% (95% CI: 25, 56) against pediatric ED visits
- Important protection against both A/H3N2 and A/H1N1 associated illness

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-02/slides-02-22/influenza-03-Olson-Lewis-Tenforde-508.pdf

School Exemptions

Measles Case Summary: Central Ohio Outbreak

(As of: Wednesday, January 25, 2023 9:56 AM)

Data Source: Ohio Disease Reporting System (ODRS). **All data are preliminary and subject to change.**

THE CITY OF COLUMBUS
ANDREW J. GINTHER, MAYOR
COLUMBUS PUBLIC HEALTH

Case Information for confirmed measles cases who are part of the current central Ohio outbreak.

Since the start of the outbreak in November 2022, we have seen:

85 cases (of which **36** were hospitalized and **0** have died)

Vaccination status

Unvaccinated	80
Partially vaccinated (1 dose)	4
Fully vaccinated (2 doses)	0
Unknown vaccination status	1

Vaccination status definitions:
Unvaccinated: Case has had 0 doses of the MMR (Measles, Mumps, and Rubella) vaccine - some cases may not have been eligible for any doses because of age
Partially vaccinated: Case has had 1 dose of the MMR vaccine - some cases may not have been eligible yet for the 2nd dose due to age
Fully vaccinated: Case has had 2 doses of the MMR vaccine

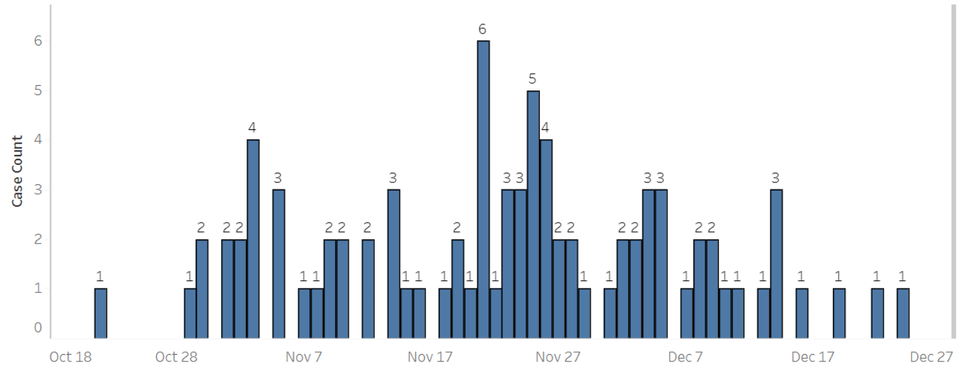
65% of cases are 1-5 years old.

<1 year old	25
1-2 years old	36
3-5 years old	19
6-17 years old	5
18+ years old	0

48% of cases are female and 52% of cases are male.

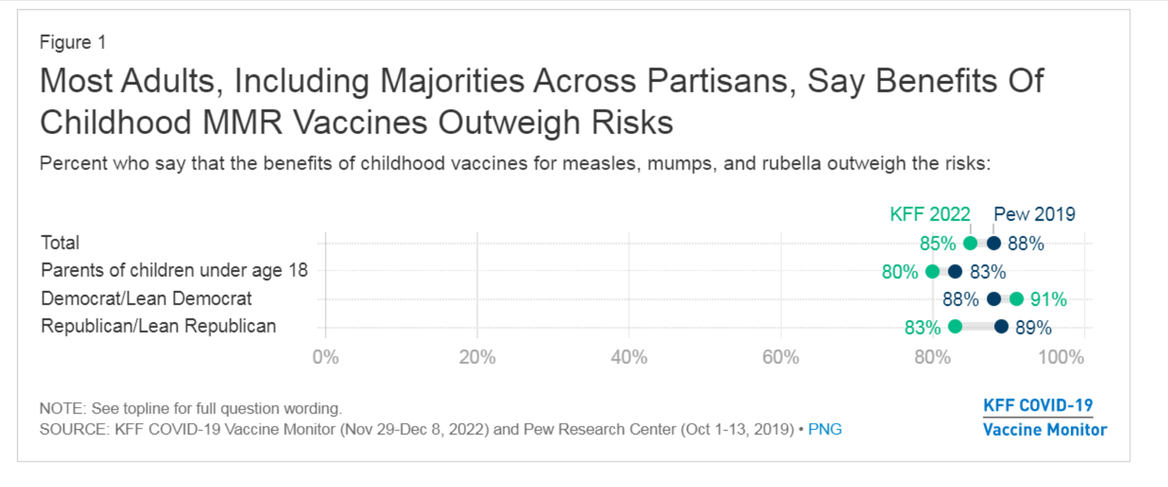
Female	41
Male	44
Unknown sex	0

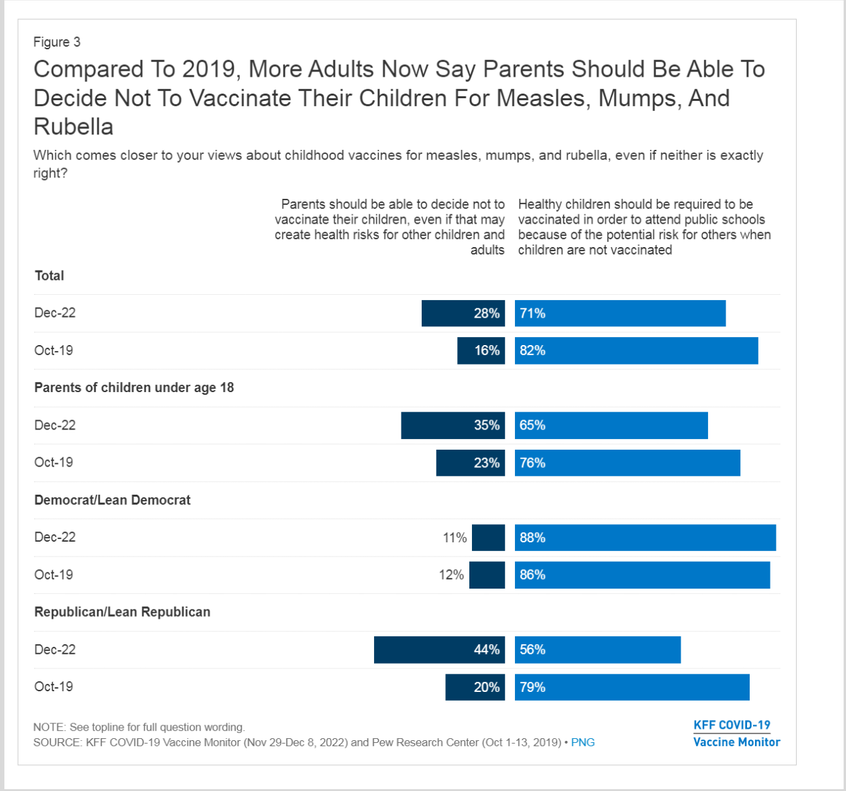
Cases by Date of Rash Onset



https://public.tableau.com/app/profile/columbus/viz/MeaslesPublicReport/MeaslesPublicReport?publish=yes

Implications





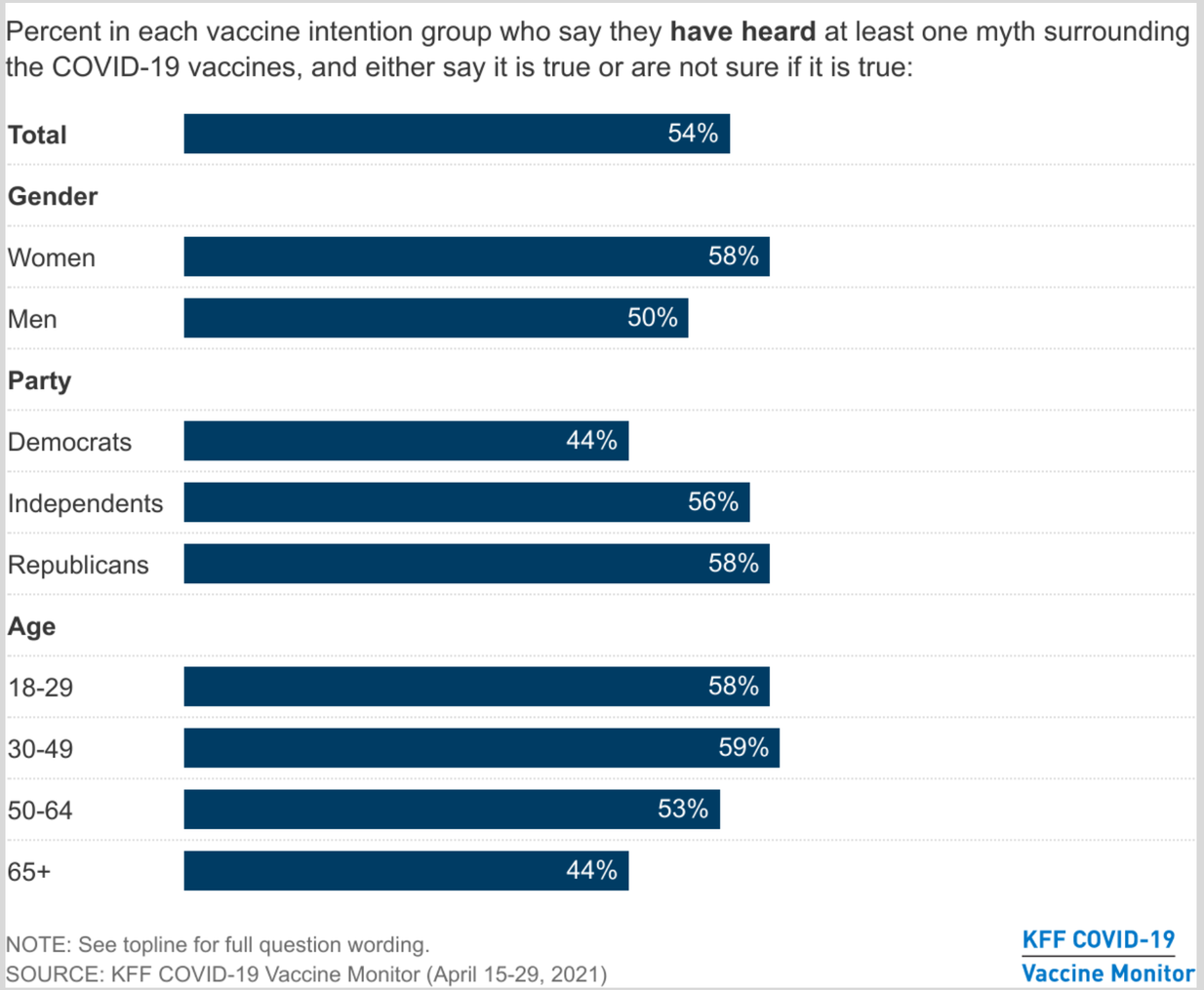
www.kff.org/coronavirus-covid-19/poll-finding/kff-covid-19-vaccine-monitor-december-2022/

Misinformation vs. Disinformation

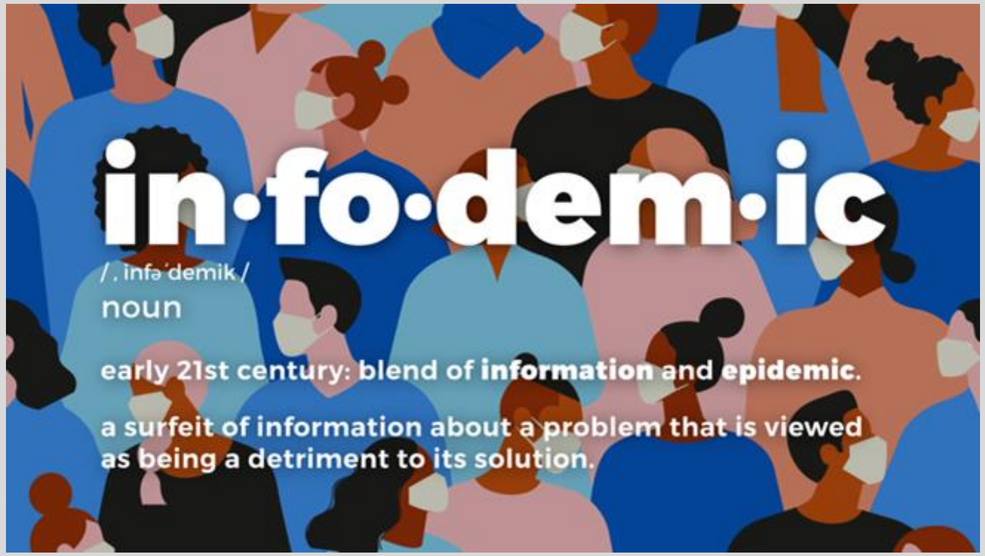
- When people spread misinformation, they often believe the information they are sharing.

- Disinformation is crafted and disseminated with the intent to mislead others.

Misinformation & Myths



Pandemic + Overload of Information = Infodemic

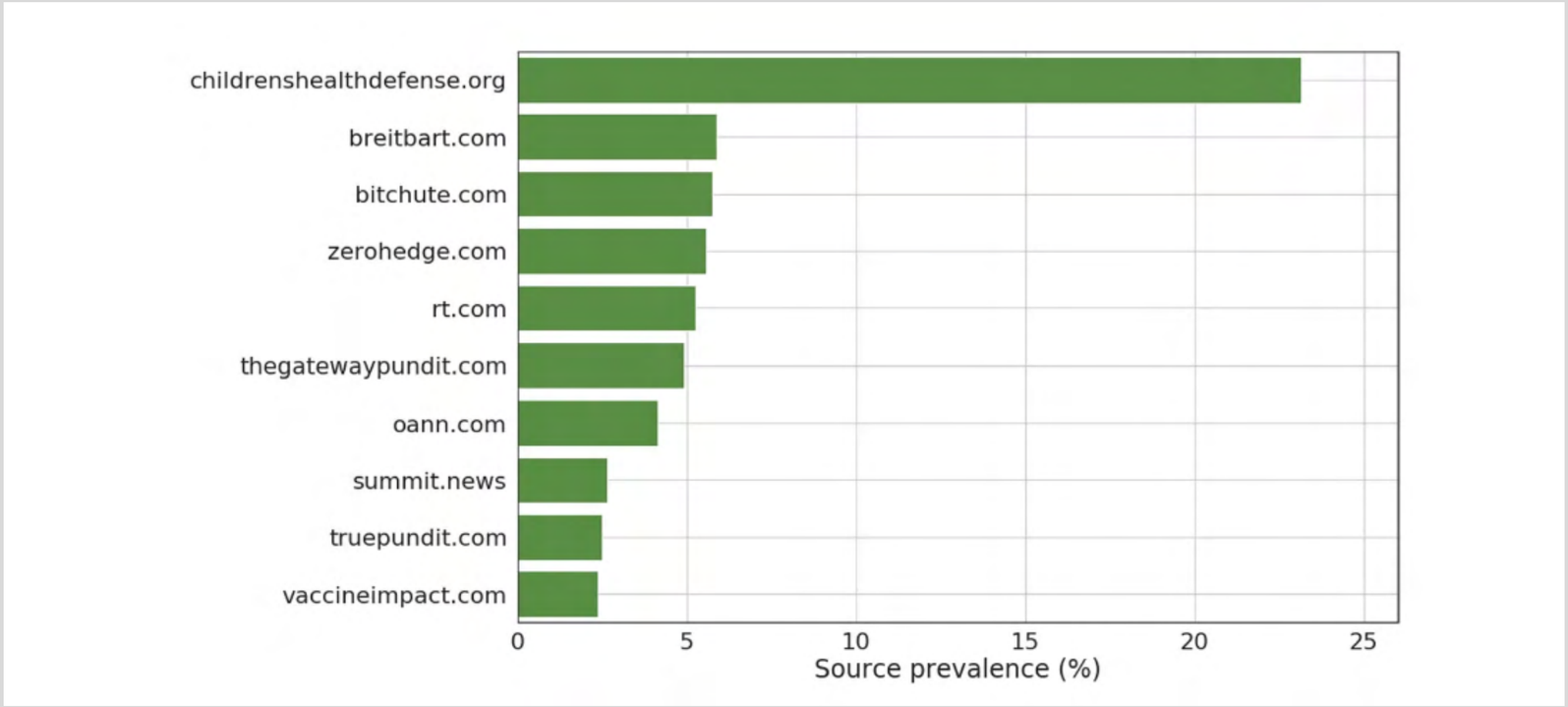


Limaye, R. J., Sauer, M., Ali, J., Bernstein, J., Wahl, B., Barnhill, A., & Labrique, A. (2020). Building trust while influencing online COVID-19 content in the social media world. *The Lancet Digital Health*, *2*(6), e277-e278.

Vaccine Landscape

“Disinformation campaigns are deliberate, often orchestrated, and highly effective in confusing people enough to change behaviors, like not getting the COVID-19 vaccine.”

Top low-credibility Sources

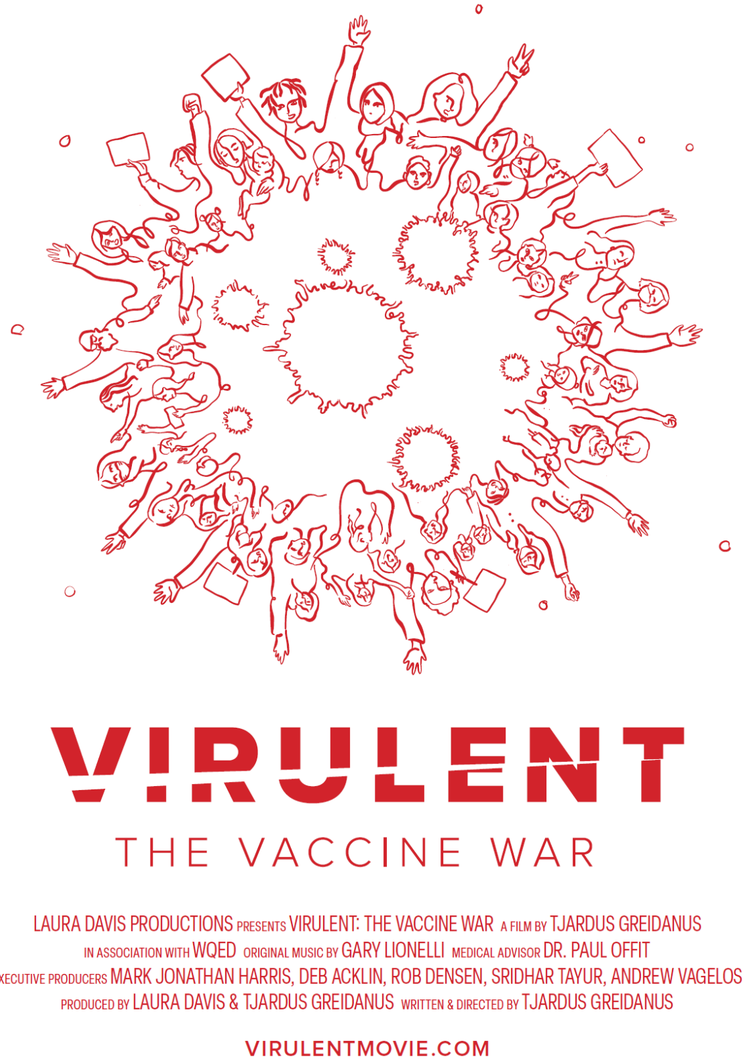


Tweets shared by users geolocated in the U.S. that link to a low-credibility source. Sources are ranked by percentage of the tweets considered.

yourlocalepidemiologist.substack.com/p/the-science-and-business-behind-covid

About the Film

Virulent: The Vaccine War



Documentary Discussion Questions

- What are your reactions to this documentary?
- What has been the most challenging part about vaccinating since 2020?
- What vaccine misinformation/disinformation patterns have you seen in the past?
  - What are the sources for this information?
  - How have these patterns changed?
- What has your clinic/organization done to respond to misinformation/disinformation?
  - Among staff (internally)
  - Among patients/families (externally)
- How do you initiate conversations about vaccines with patients?
  - How do you address misinformation/myths with a patient?
  - How do you address vaccine hesitancy?
- What strategies to address vaccine hesitancy have worked?
  - What hasn’t worked?

Next Steps

- Make sure you signed in
- Fill out your evaluation (needed for CME)
- Let us know if you want additional outreach materials

SCAN ME

JOIN ICAAP FOR THE 2023

ANNUAL EDUCATION CONFERENCE

November 9 &10, 2023
Northern Illinois University Naperville

Illinois Chapter
INCORPORATED IN ILLINOIS
American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

- ⇒ Network and earn CME.
- ⇒ Hear the latest on “hot topics” and recent practical advances on a variety of subspecialty areas.
- ⇒ Keynote topics include:
  Pediatric Firearm Injuries and Fatalities
  &
  Pediatric Mental Health

Register today!

SCAN ME

Thank You