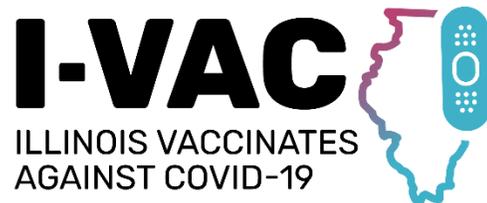




# Planning for the Bivalent COVID-19 Vaccine Rollout

Part Two – September 9, 2022 – **starting at 12:05pm**





# On Today's Call

- ▷ Illinois Department of Public Health: Karyn Lyons
- ▷ Chicago Department of Public Health: Maribel Chavez-Torres and Kevin Hansen
- ▷ ICAAP: Rachel Caskey, MD, MPP and Stephanie Atella



## Details & Eligibility

- ▷ Administered as single dose booster to people who previously **completed a primary COVID-19 vaccination series**
- ▷ Number of previous boosters received **does not matter**
- ▷ Ages
  - ▷ 12 years+ (Pfizer)
  - ▷ 18 years+ (Moderna)
  - ▷ Expected that at least one bivalent vaccine for children ages 11 years and younger may be authorized within a short time following the authorization(s) for older age groups



## Details & Eligibility

- ▷ Monovalent mRNA CVOID-19 vaccines are NO LONGER authorized for use as boosters in people ages 12 years and older.
- ▷ No changes have been made to primary vaccines products.
- ▷ No changes have been made to the schedule for 6 months to 11-year-olds.
  - ▷ Those 5 years to 11 years can still be given the original (or monovalent) Pfizer vaccines as a booster.



# Storage & Handling Pfizer

Age Indications	6 months through 4 years	5 years through 11 years	12 years and older	12 years and older
Formulation	Primary Series	Primary Series and Booster Dose	Primary Series	Single Bivalent Booster Dose
Vial Cap Color/Label with Color Border	Maroon	Orange	Gray	Gray
Preparation	Dilute Before Use	Dilute Before Use	Do Not Dilute	Do Not Dilute
Amount of Diluent Needed per Vial <sup>a</sup>	2.2 mL	1.3 mL		
Dose Volume/Dose	0.2 mL/3 mcg	0.2 mL/10 mcg	0.3 mL/30 mcg	0.3 mL/30 mcg
Doses per Vial	10 primary (after dilution)	10 primary/booster (after dilution)	6 primary	6 booster
ULT Freezer (-90°C to -60°C) <sup>b</sup>	12 months			
Freezer (-25°C to -15°C)	DO NOT STORE			
Refrigerator (2°C to 8°C)	10 weeks			
Room Temperature (8°C to 25°C) including any thaw time	12 hours prior to first puncture			
After First Puncture (2°C to 25°C)	Discard after 12 hours			

<sup>a</sup> Diluent: Sterile 0.9% Sodium Chloride Injection, USP. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.

<sup>b</sup> Regardless of storage condition, vaccines should not be used after 12 months from the date of manufacture printed on the vial and cartons.



# Storage & Handling Moderna

Age Indications and Formulation	6 months through 5 years (Primary Series)	6 years through 11 years (Primary Series)*	12 years and older (Primary Series)**	18 years and older (Single Bivalent Booster Dose)
Vial Cap Color	Dark blue	Dark blue	Red (5.5 mL)	Dark blue
Vial Label Border Color	Magenta	Purple	Light Blue	Gray
Preparation	Do Not Dilute	Do Not Dilute	Do Not Dilute	Do Not Dilute
Dose Volume/Dose	0.25 mL/25 mcg	0.5 mL/50 mcg	0.5 mL/100 mcg primary	0.5 mL/50 mcg
Doses per Vial	10 primary	5 primary	11 max primary	5 booster
ULT Freezer (-90°C to -60°C)	DO NOT STORE			
Freezer (-50°C to -15°C) <sup>a</sup>	Until Expiration			
Refrigerator (2°C to 8°C)	30 Days			
Room Temperature (8°C to 25°C) <b>including any thaw time</b>	24 hours			
After First Puncture (2°C to 25°C) <sup>b</sup>	Discard after 12 hours			

<sup>a</sup> Regardless of storage condition, vaccines should not be used after the expiration date. <sup>b</sup> After a vial is punctured 20 times it should be discarded even if the 12-hour time limit has not been met. \*Can be used as a dose in those who received a J & J primary dose. \*\* Although labels may state “booster doses only”, the blue cap, purple label border presentation is suitable for use as a primary dose in ages 6-11



# Factsheets/VISs

## Moderna

- ▷ [FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE \(VACCINATION PROVIDERS\)](#)
- ▷ [VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS](#)

## Pfizer

- ▷ [FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE \(VACCINATION PROVIDERS\)](#)
- ▷ [VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS](#)



# Bivalent Packing

XXXXXX

STORE FROZEN between -50° to -15°C (-58° to 5°F). Protect from light. No preservative. After first use, hold at 2° to 25°C (36° to 77°F). Discard after 12 hours.

Record date/time of first use: \_\_\_\_\_

Scan for expiry date, FDA-authorized Fact Sheet and dose volume

**Moderna COVID-19 Vaccine, Bivalent Original and Omicron BA.4/BA.5**

Suspension for Intramuscular Injection  
For use under Emergency Use Authorization

**BOOSTER DOSES ONLY**

Multi-Dose Vial  
Booster dose: 0.5 mL or 0.25 mL based on age

NDC 80777-282-05

LOT

LOT/MFG: PAA194854

**Pfizer-BioNTech COVID-19 Vaccine, Bivalent Original and Omicron BA.4/BA.5**

**DO NOT DILUTE** Age 12y & older  
Vial contains 6 doses of 0.3 mL  
For intramuscular use. Contains no preservative. For use under Emergency Use Authorization. After first use store at 2 to 25°C (35 to 77°F) and discard after 12 hours.  
First use date and time: \_\_\_\_\_

NDC 59267-0304-1



# Ordering Information

	<b>Pfizer</b>	<b>Moderna</b>
<b>Formulation</b>	<b>Bivalent Booster</b>	<b>Bivalent Booster</b>
<b># vials per tray</b>	<b>10</b>	<b>10</b>
<b># doses per tray</b>	<b>60</b>	<b>50</b>
<b>Minimum order quantity</b>	<b>5 trays (300 doses)</b>	<b>2 trays (100 doses)</b>
<b>Delivery time</b>	<b>~1 week</b>	

Ancillary supplies will be provided for bivalent products, including a variety of 1-inch and 1.5-inch needles and syringes. Opt-out is available.



# Orders

- ▷ Chicago Locations (CDPH) Chicago COVID-19 vaccine providers can request bivalent booster doses on the routine vaccine ordering survey [here](#).



# Orders

- ▷ Non-Chicago Locations (IDPH) via I-CARE.



## Additional Information

- ▷ Provider facilities that do not require minimum order quantities should contact their local health department or other typical sources for vaccine redistribution, such as the [State Vaccine Reallocation Tool](#)
- ▷ Providers are asked to report their inventory to Vaccines.gov as soon as possible – **include ages please!**



## Reminder

- ▷ Some wastage is expected in order to vaccinate all eligible Illinoisians.
- ▷ Providers will NOT be penalized for wasting the remainder of a vial if they are only able to utilize a portion of the doses in the vial.



# COVID-19 Vaccination Record Cards

If vaccination card is full:

- ▷ CDC recommends completing a second card and stapling the two cards together.
- ▷ Encourage the patient to photograph both cards in case the two become separated, if possible.
- ▷ Both cards should be presented when vaccination history is required for travel, employment, or other purposes.
- ▷ Encourage patients to download their vaccine records with VaxVerify.



## FAQs

### Is the bivalent booster available to uninsured patients free of charge?

- ▷ Yes. The vaccine itself still cannot be charged for. While the HRSA (federal) uninsured program has come to an end, the Illinois Department of Healthcare and Family Services (HFS) (state) has continued funding and more information about vaccinating the insured and reimbursement for administration and vaccine counseling is available [here](#).

Related: Getting Paid for COVID-19 vaccines [article](#) from the AAP



# Questions

- ▷ Related to storage & handling
- ▷ Ordering

**NEXT SECTION IS ON CLINICAL GUIDANCE**



## FAQs

### **Do patients have the option to decide which booster dose they may receive (original vs updated)?**

- ▷ No. Monovalent mRNA COVID-19 vaccines are NO LONGER authorized for use as boosters in people ages 12 years and older.



# FAQs

## Most commonly reported symptoms?

They are similar to the monovalent COVID-19 vaccines:

- ▷ Muscle pain
- ▷ Chills
- ▷ Joint pain
- ▷ Fever
- ▷ Headache
- ▷ Pain, redness and swelling at the injection site
- ▷ Fatigue



# FAQs

## What safety data do we have?

- ▷ Both Moderna and Pfizer have shared data on the safety of the BA.1 bivalent vaccine on over 1,400 adults.
  - ▷ The bivalent vaccine that will be available in the US is the BA.5 bivalent vaccine, but the differences between the two (BA.1 and BA.5) is very small.
  - ▷ According to Your Local Epidemiologist, "The difference is a few amino acids or equivalent to a few letter edits on a Word document. We aren't changing the number of words in the paper (like dosage of RNA), or the content of the paper, or the platform (like Word to Excel). Because of the minimal change, we are confident that BA.1 bivalent safety data will accurately reflect BA.5 safety. The risk of myocarditis after COVID-19 infection (compared to vaccination) is 1.8 - 5.6 times higher among young males."



# FAQs

## Can patients mix and match products?

▷ For booster vaccination, age-appropriate mRNA vaccines are recommended. Any homologous or heterologous age-appropriate mRNA vaccine can be used if a booster dose is FDA-authorized for use in a specified population.

- Homologous booster dose:** The same vaccine manufacturer used for the booster dose and the primary series.

- Heterologous booster dose (mix-and-match booster):** A different vaccine manufacturer used for the booster dose and the primary series.



# Other 9.2.22 Updates

## History of MIS-C or MIS-A

- ▷ The benefits outweigh a theoretical risk of a MIS-like illness for people who meet all the following criteria:
  - 1) Clinical recovery has been achieved, including return to normal cardiac function;
  - 2) It has been  $\geq 90$  days since their diagnosis of MIS-C;

Experts view clinical recovery, including return to baseline cardiac function, as an important factor when considering COVID-19 vaccination. Additional factors, such as the risk of severe COVID-19 due to age or [certain medical conditions](#), may also be considered.

- Initiation of COVID-19 vaccination in people with a history of MIS-C/A should take into consideration current or planned immunomodulatory therapies for treatment of MIS-C/A (see [Considerations for timing of COVID-19 vaccination in relation to immunosuppressive therapies](#)).



# Other 9.2.22 Updates

## Post-vaccination observation period

- ▷ Vaccination providers, particularly when vaccinating adolescents, should consider observing vaccine recipients for 15 minutes after vaccination. If syncope develops, patients should be observed until symptoms resolve.
- ▷ Additionally, providers should consider observing people with the following medical histories for 30 minutes after COVID-19 vaccination to monitor for allergic reactions:
  - Allergy-related contraindication to a different type of COVID-19 vaccine
  - Non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of COVID-19 vaccine.
  - Anaphylaxis after non-COVID-19 vaccines or injectable therapies



# PFIZER-BIONTECH COVID-19 VACCINATION SCHEDULE AND DOSING

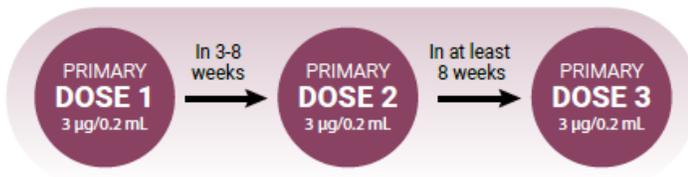
## FOR NON-IMMUNOCOMPROMISED POPULATIONS



### Pfizer-BioNTech Ages 6 months–4 years

dose/injection volume  
(dilute before use)

**Primary Dose:**  
Maroon Cap



### Pfizer-BioNTech Ages 5 years–11 years

dose/injection volume  
(dilute before use)

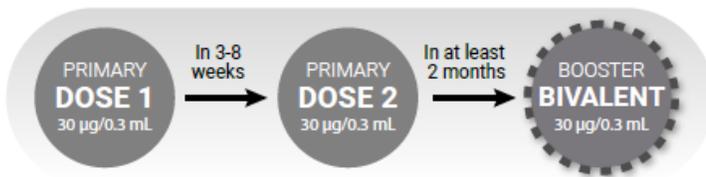
**Primary/Booster Dose:**  
Orange Cap



### Pfizer-BioNTech Ages 12 years–17 years

dose/injection volume  
(Do NOT dilute before use)

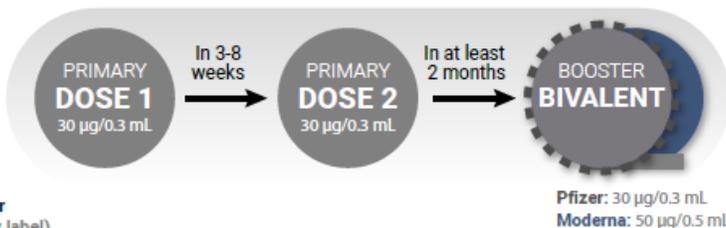
**Primary Dose:**  
Gray Cap  
**Bivalent Booster:**  
Gray Cap (gray label)



### Pfizer-BioNTech Ages 18 years and older

dose/injection volume  
(Do NOT dilute before use)

**Primary Dose:**  
Gray Cap  
**Bivalent Booster:**  
PFIZER Gray Cap (gray label) or  
MODERNA Dark Blue Cap (gray label)



See the [Pfizer-BioNTech COVID-19 Vaccine Guidance](#) for children who are transitioning from a younger to older age group during their vaccination window.

\* Complete the primary series with same product. If the vaccine product previously administered cannot be determined or is no longer available, any age-appropriate mRNA COVID-19 vaccine product may be administered at least 28 days after the first dose.

† Persons with a recent SARS-CoV-2 infection may consider delaying a primary series or booster dose by 3 months from symptom onset or positive test (if infection was asymptomatic).

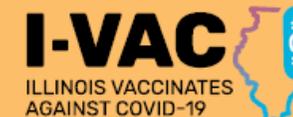
‡ Some studies in adolescents and adults have shown the small risk of myocarditis associated with mRNA COVID-19 vaccines might be reduced and peak antibody responses and vaccine effectiveness may be increased with an interval longer than 4 weeks. An 8-week interval may be optimal for people who are not moderately or severely immunocompromised and ages 6 months–64 years, especially for males ages 12–39 years. Source: [CDC](#).

See the [CDC's Guidance](#) for latest updates and information on who is considered moderately or severely immunocompromised.



# PFIZER-BIONTECH COVID-19 VACCINATION SCHEDULE AND DOSING

## FOR IMMUNOCOMPROMISED POPULATIONS



### Pfizer-BioNTech Ages 6 months–4 years

dose/injection volume  
(dilute before use)

**Primary Dose:**  
Maroon Cap



### Pfizer-BioNTech Ages 5 years–11 years

dose/injection volume  
(dilute before use)

**Primary/Booster Dose:**  
Orange Cap



### Pfizer-BioNTech Ages 12 years–17 years

dose/injection volume  
(Do NOT dilute before use)

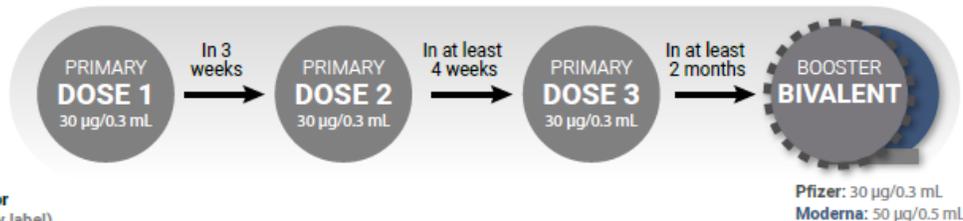
**Primary Dose:**  
Gray Cap  
**Bivalent Booster:**  
Gray Cap (gray label)



### Pfizer-BioNTech Ages 18 years and older

dose/injection volume  
(Do NOT dilute before use)

**Primary Dose:**  
Gray Cap  
**Bivalent Booster:**  
PFIZER Gray Cap (gray label) or  
MODERNA Dark Blue Cap (gray label)



\* Complete the primary series with same product. If the vaccine product previously administered cannot be determined or is no longer available, any age-appropriate mRNA COVID-19 vaccine product may be administered at least 28 days after the first dose.

† Persons with a recent SARS-CoV-2 infection may consider delaying a primary series or booster dose by 3 months from symptom onset or positive test (if infection was asymptomatic).

‡ Some studies in adolescents and adults have shown the small risk of myocarditis associated with mRNA COVID-19 vaccines might be reduced and peak antibody responses and vaccine effectiveness may be increased with an interval longer than 4 weeks. An 8-week interval may be optimal for people who are not moderately or severely immunocompromised and ages 6 months–64 years, especially for males ages 12–39 years. Source: [CDC](#).

See the [CDC's Guidance](#) for latest updates and information on who is considered moderately or severely immunocompromised.

# MODERNA COVID-19 VACCINATION SCHEDULE AND DOSING

## FOR NON-IMMUNOCOMPROMISED POPULATIONS

### Moderna

#### Ages 6 months–5 years

dose/injection volume  
(Do NOT dilute before use)

Primary Dose:

Blue Cap (magenta label)



### Moderna

#### Ages 6 years–11 years

dose/injection volume  
(Do NOT dilute before use)

Primary Dose:

Blue Cap (purple label)



### Moderna

#### Ages 12 years–17 years

dose/injection volume  
(Do NOT dilute before use)

Primary Dose:

Red Cap (blue label)

PFIZER ONLY Bivalent Booster:

Gray Cap (gray label)



### Moderna

#### Ages 18 years and older

dose/injection volume  
(Do NOT dilute before use)

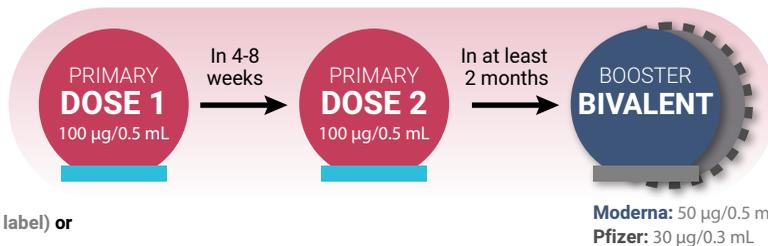
Primary Dose:

Red Cap (blue label)

Bivalent Booster:

MODERNA Dark Blue Cap (gray label) or

PFIZER Gray Cap (gray label)



\* Complete the primary series with same product. If the vaccine product previously administered cannot be determined or is no longer available, any age-appropriate mRNA COVID-19 vaccine product may be administered at least 28 days after the first dose.

† Persons with a recent SARS-CoV-2 infection may consider delaying a primary series or booster dose by 3 months from symptom onset or positive test (if infection was asymptomatic).

‡ Some studies in adolescents and adults have shown the small risk of myocarditis associated with mRNA COVID-19 vaccines might be reduced and peak antibody responses and vaccine effectiveness may be increased with an interval longer than 4 weeks. An 8-week interval may be optimal for people who are not moderately or severely immunocompromised and ages 6 months–64 years, especially for males ages 12–39 years. Source: [CDC](https://www.cdc.gov/media/releases/2022/s0927-covid19-vaccine-interval.html).



See the [Moderna COVID-19 Vaccine Guidance](#)

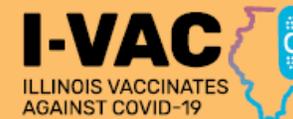
for children who are transitioning from a younger to older age group during their vaccination window.

See the [CDC's Guidance](#) for latest updates and information on who is considered moderately or severely immunocompromised.



# MODERNA COVID-19 VACCINATION SCHEDULE AND DOSING

## FOR IMMUNOCOMPROMISED POPULATIONS



### Moderna Ages 6 months–5 years

dose/injection volume  
(Do NOT dilute before use)

Primary Dose:  
Blue Cap (magenta label)



### Moderna Ages 6 years–11 years

dose/injection volume  
(Do NOT dilute before use)

Primary Dose:  
Blue Cap (purple label)



### Moderna Ages 12 years–17 years

dose/injection volume  
(Do NOT dilute before use)

Primary Dose:  
Red Cap (blue label)

PFIZER ONLY Bivalent Booster:  
Gray Cap (gray label)

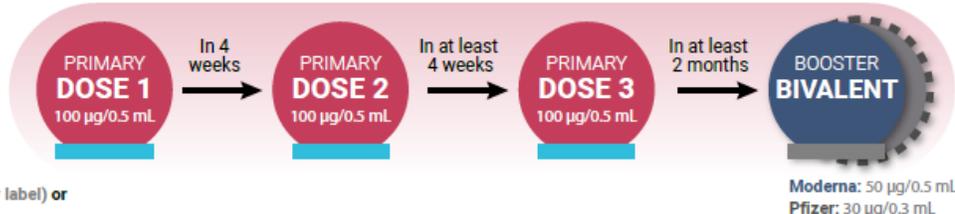


### Moderna Ages 18 years and older

dose/injection volume  
(Do NOT dilute before use)

Primary Dose:  
Red Cap (blue label)

Bivalent Booster:  
MODERNA Dark Blue Cap (gray label) or  
PFIZER Gray Cap (gray label)



\* Complete the primary series with same product. If the vaccine product previously administered cannot be determined or is no longer available, any age-appropriate mRNA COVID-19 vaccine product may be administered at least 28 days after the first dose.

† Persons with a recent SARS-CoV-2 infection may consider delaying a primary series or booster dose by 3 months from symptom onset or positive test (if infection was asymptomatic).

‡ Some studies in adolescents and adults have shown the small risk of myocarditis associated with mRNA COVID-19 vaccines might be reduced and peak antibody responses and vaccine effectiveness may be increased with an interval longer than 4 weeks. An 8-week interval may be optimal for people who are not moderately or severely immunocompromised and ages 6 months–64 years, especially for males ages 12–39 years. Source: [CDC](https://www.cdc.gov).

See the [CDC's Guidance](https://www.cdc.gov) for latest updates and information on who is considered moderately or severely immunocompromised.



# OTHER COVID-19 VACCINATION SCHEDULE AND DOSING

## FOR NON-IMMUNOCOMPROMISED POPULATIONS

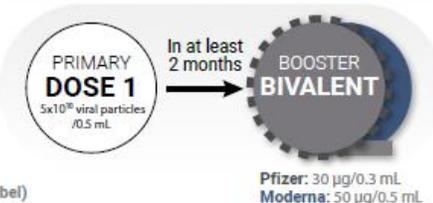


### Janssen (J&J) Ages 18 years and older

dose/injection volume  
(dilute before use)

#### Bivalent Boosters:

Pfizer Gray Cap (gray label) or  
Moderna Dark Blue Cap (gray label)

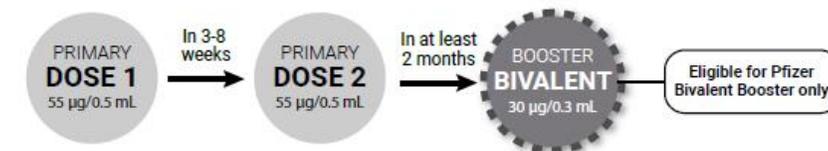


### Novavax Ages 12 years–17 years

dose/injection volume

#### Bivalent Boosters:

Pfizer Gray Cap (gray label)

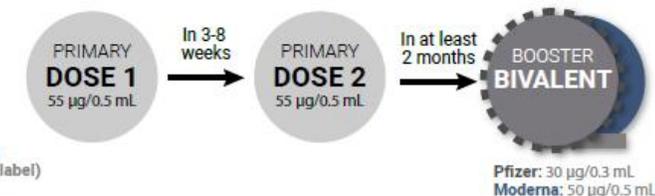


### Novavax Ages 18 years and older

dose/injection volume

#### Bivalent Boosters:

PFIZER Gray Cap (gray label) or  
MODERNA Dark Blue Cap (gray label)



▶ All charts are available at [illinoisvaccinates.com/resources](https://illinoisvaccinates.com/resources)

## FOR IMMUNOCOMPROMISED POPULATIONS

### Janssen (J&J) Ages 18 years and older

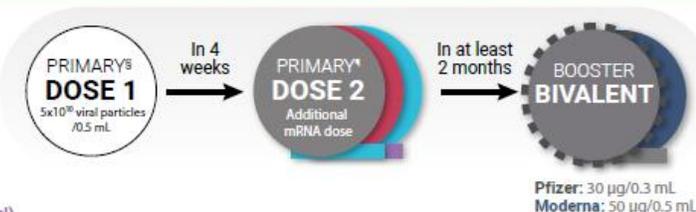
dose/injection volume  
(dilute before use)

#### Primary Dose:

Pfizer's Gray Cap  
Moderna's Red Cap (blue label)  
Moderna's Blue Cap (purple label)

#### Bivalent Boosters:

PFIZER Gray Cap (gray label) or  
MODERNA Dark Blue Cap (gray label)



§ Age-appropriate mRNA COVID-19 vaccines are preferred over the Janssen COVID-19 Vaccine for all vaccine doses for all vaccine-eligible people 18 years of age and older. Janssen COVID-19 vaccine should only be used in limited situations. See [CDC](https://www.cdc.gov).

¶ mRNA vaccine must be used.

Source: [COVID-19 Vaccine Interim COVID-19 Immunization Schedule for 6 Months of Age and Older](https://www.cdc.gov/vaccines/imz/downloads/pdf/covid-19-2022-01.pdf)

See the [CDC's Guidance](https://www.cdc.gov) for latest updates and information on who is considered moderately or severely immunocompromised.

[illinoisvaccinates.com](https://illinoisvaccinates.com)



# Upcoming Trainings and Support

Tuesday	September 13	12 pm–1 pm	Dr. Anne Schneider
Thursday	September 22	12 pm–1 pm	Dr. Anita Chandra-Puri
Tuesday	September 27	12 pm–1 pm	Dr. Alex Albanese
Tuesday	October 4	12 pm–1 pm	Dr. Andrea Kane
Friday	October 14	12 pm–1 pm	Dr. Anna Volerman
Thursday	October 20	12 pm–1 pm	Dr. Craig Batterman
Tuesday	October 25	12 pm–1 pm	Dr. Carissa Lee Holmes

## ▷ I-VAC Office Hours

▷ Follow [this link](#) to join on Zoom

## ▷ Moderna

▷ Trainings [link](#)

▷ Office hours and regional contacts [link](#)

## ▷ Pfizer

▷ Trainings [link](#)



# Resources

- ▷ Updated standing orders
  - ▷ [Moderna](#)
  - ▷ [Pfizer](#)
- ▷ [Illinois Vaccinates Against COVID-19 \(I-VAC\)](#)
  - ▷ Bivalent social media images available
- ▷ Provider FAQs [here](#)
- ▷ Patient-Facing COVID-19 Vaccine FAQs
  - ▷ On pediatric COVID-19 vaccines [here](#)
  - ▷ On bivalent vaccines [here](#) (available in English and Spanish)
- ▷ AAP dosing guide for when a child has birthdays in between doses [here](#)



**Friday, September 23<sup>rd</sup> from 8am-12:15pm**

**Register at [illinoisvaccinates.com/bootcamps](https://illinoisvaccinates.com/bootcamps)**



# Contact Information

## IDPH

- ▷ To enroll in I-CARE: [dph.immunizations@illinois.gov](mailto:dph.immunizations@illinois.gov)
- ▷ For questions about vaccine orders: [dph.vaccines@illinois.gov](mailto:dph.vaccines@illinois.gov)

## CDPH

- ▷ Kevin Hansen: [Kevin.Hansen@cityofchicago.org](mailto:Kevin.Hansen@cityofchicago.org)
- ▷ Provider resources: <https://www.chicagohan.org/covid-19-vaccine/provider>

## ICAAP/I-VAC

- ▷ [Illinois Vaccinates Against COVID-19](#)
- ▷ Stephanie Atella: [satella@illinoisAAP.com](mailto:satella@illinoisAAP.com)
- ▷ [Facts@ilvaccinates.com](mailto:Facts@ilvaccinates.com)

## Pfizer

- ▷ Customer Service: Call 1-800-879-3477
- ▷ General Product Inquiries: Call 1-877-829-2619
- ▷ Pfizer Medical Information: Call 1-800-438-1985 or Visit [PfizerMedicalInformation.com](https://PfizerMedicalInformation.com)
- ▷ Controlant Customer Support: 1-701-540-4039
- ▷ Pfizer US Shipment Support: Call 1-800-666-7248

## Moderna

- ▷ Customer Service: Call 1-866-MODERNA (1-866-663-3762) or Email [ModernaPV@modernatx.com](mailto:ModernaPV@modernatx.com)
- ▷ Chatbot [here](#)