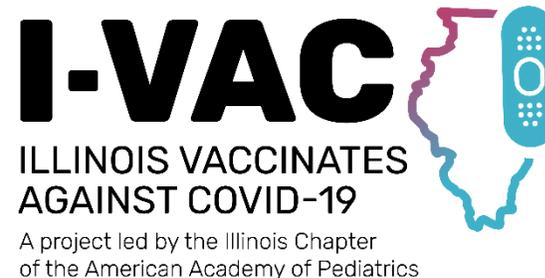




Planning for the Pediatric Bivalent COVID-19 Booster Rollout

September 29, 2022





On Today's Call

- ▷ Illinois Department of Public Health
- ▷ Chicago Department of Public Health
- ▷ ICAAP/I-VAC: Dr. Christina Wells



Administration of bivalent boosters to children 5-11 years old cannot begin until after FDA EUA is issued AND a CDC recommendation is granted.

All information is subject to change.



What is a Bivalent COVID-19 Vaccine?

- ▷ *From Moderna:* Bivalent vaccines are designed to protect against two strains of a virus providing greater protection against variants compared to the original Moderna COVID-19 Vaccine.
- ▷ *From Pfizer:* The Omicron BA.4/BA.5-adapted bivalent vaccine contains mRNA encoding the wild-type spike protein of SARS-CoV-2 in the Original Pfizer-BioNTech COVID-19 Vaccine, and mRNA encoding the spike protein of the Omicron BA.4/BA.5 subvariants. Apart from the addition of the mRNA sequence of the BA.4/BA.5 spike protein, all other components of the vaccine remain unchanged.



Pediatric Bivalent COVID-19 Boosters

- ▷ If authorized by FDA, CDC anticipates a recommendation for bivalent COVID-19 vaccine as a booster for pediatric age groups in early to mid-October.
 - ▷ ACIP meetings scheduled for: October 19-20
- ▷ Ages and products:
 - ▷ [Pfizer-BioNTech](#): for children 5-11 years
 - ▷ [Moderna](#): for children 6-17 years

UPDATED: September 20, 2022: CDC Fall Vaccination Operational Planning Guide
Information for the Fall Vaccine Campaign, Including Upcoming Pediatric Bivalent COVID-19 Vaccine as Boosters for Children
Aged 5-11 Years



Anticipated Guidance

- ▷ Pediatric bivalent COVID-19 vaccines will be:
 - ▷ A single booster dose in children who have completed a primary vaccination series **at a minimum interval** after their last COVID-19 dose.
- ▷ It is expected that heterologous (mix-and-match) bivalent vaccines will be authorized, e.g.:
 - ▷ Children who completed a primary series of Pfizer-BioNTech vaccine would be able to receive a bivalent Moderna vaccine (or vice versa).
 - ▷ Adolescents 12-17 years old will have the option of receiving either Moderna or Pfizer bivalent vaccine.

[UPDATED: September 20, 2022: CDC Fall Vaccination Operational Planning Guide
Information for the Fall Vaccine Campaign, Including Upcoming Pediatric Bivalent COVID-19 Vaccine as Boosters for Children
Aged 5-11 Years](#)



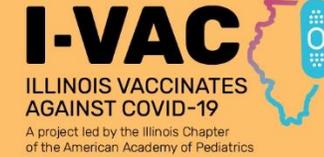
Anticipated Guidance

- ▷ Monovalent mRNA COVID-19 vaccines would NO LONGER be authorized for use as boosters in children 5 years and older.
- ▷ No changes to primary vaccine products.
- ▷ No changes to the schedule for 6 months to 4 years-old.

[UPDATED: September 20, 2022: CDC Fall Vaccination Operational Planning Guide Information for the Fall Vaccine Campaign, Including Upcoming Pediatric Bivalent COVID-19 Vaccine as Boosters for Children Aged 5-11 Years](#)

STORAGE & HANDLING

PFIZER-BIONTECH STORAGE & HANDLING INFORMATION



AGE INDICATIONS	6 months through 4 years	5 years through 11 years	5 years through 11 years	12 years and older	12 years and older
FORMULATION	Primary Series	Primary Series	Single Bivalent Booster Dose	Primary Series	Single Bivalent Booster Dose
VIAL CAP COLOR/LABEL WITH COLOR BORDER	Maroon	Orange	Orange/ Bivalent label	Gray	Gray
PREPARATION	Dilute Before Use	Dilute Before Use	Dilute Before Use	Do Not Dilute	Do Not Dilute
AMOUNT OF DILUENT NEEDED PER VIAL ^a	2.2 mL	1.3 mL	1.3 mL		
DOSE VOLUME/DOSE	0.2 mL/3 mcg	0.2 mL/10 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 (after dilution)	10 booster (after dilution)	6 primary	6 booster
ULT FREEZER (-90°C TO -60°C) ^b	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				

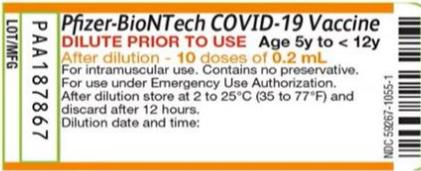
^a Diluent: Sterile 0.9% Sodium Chloride Injection, USP. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.

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

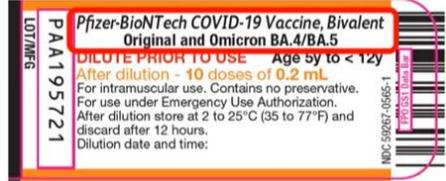
Pending Authorization



**Pfizer-BioNTech COVID-19 Vaccine
Primary Series Only***



**Pfizer-BioNTech COVID-19 Vaccine, Bivalent
(Original and Omicron BA.4/BA.5)
Booster Dose Only***



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

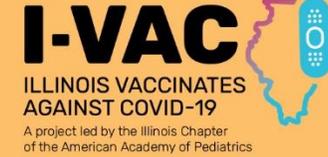


Multiple-Dose Vial THAW TIME	
Refrigerator (2°C to 8°C)	Up to 4 hours
Room Temperature (up to 25°C)	30 minutes

- ✓ After dilution with 1.3 mL of 0.9% Sodium Chloride Injection, USP the vial contains 10 doses of 0.2 mL (10 mcg)
- ✓ Prior to withdrawing a dose, check that the vial has not reached the 12-hour post-dilution expiration
- ✓ Withdraw 0.2 mL dose (10 mcg) of Orange Cap vaccine for administration to individuals 5 through 11 years of age
- ✓ Any vaccine remaining in vials (or syringes) should be discarded 12 hours after dilution

STORAGE & HANDLING

MODERNA STORAGE & HANDLING INFORMATION



AGE INDICATIONS AND FORMULATION	6 months through 5 years (Primary Series)	6 years through 11 years (Primary Series)*	12 years and older (Primary Series)**	6 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	<ul style="list-style-type: none"> 6 to 11 years old: 0.25 mL/25 mcg 12 years and older: 0.5 mL/50 mcg
DOSES PER VIAL	10 primary doses	5 primary doses	11 max primary doses	Varies by age: <ul style="list-style-type: none"> 6 to 11 years old: 10 booster doses 12 years and older: 5 booster doses
ULT FREEZER (-90°C TO -60°C)	DO NOT STORE			
FREEZER (-50°C TO -15°C) ^a	Until expiration			
REFRIGERATOR (2°C TO 8°C)	30 days			
ROOM TEMPERATURE (8°C TO 25°C) including any thaw time	24 hours			
AFTER FIRST PUNCTURE (2°C TO 25°C) ^b	Discard after 12 hours			

^a Regardless of storage condition, vaccines should not be used after the expiration date.

^b 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 only for use as a *primary* dose in ages 6-11

Pending Authorization

Pending Authorization

Ordering Information

	Pfizer	Pfizer*	Moderna*
Formulation	Bivalent Booster 5-11	Bivalent Booster 12+	Bivalent Booster 6+
# vials per tray	10	10	10
# doses per tray	100	60	50
Minimum order quantity	1 tray (100 doses)	5 trays (300 doses)	2 trays (100 doses)
Delivery time	~1 week		

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 for Pfizer 12+ bivalent and Moderna – NOT for 5-11 bivalent.



Ancillary Kits

- ▷ Bivalent Moderna COVID-19 vaccines for children aged 6-11 years, if authorized.
 - ▷ 2 ancillary kits per minimum dose order will be sent to accommodate double the number of doses provided in each vial.
- ▷ Upon Moderna authorization, providers will need to specify pediatric intent within their vaccine order process to receive the appropriate ancillary kit.
- ▷ An ancillary opt-out continues to be available for all **non-diluent kits**.



Ordering

IDPH

- ▷ Pre-ordering is open now in I-CARE for Pfizer COVID-19 Bivalent for ages 5-11 years.
- ▷ Ordering for Moderna COVID-19 bivalent for ages 6-17 years will occur post-EUA.



Ordering

▷ CDPH

▷ Reach out to COVID19vaccine@cityofchicago.org



Pfizer

Pfizer-BioNTech Ages 6 months–4 years

dose/injection volume
(dilute before use)

Primary Dose:
Maroon Cap



Pfizer-BioNTech 5 year olds ONLY

dose/injection volume
(dilute before use)

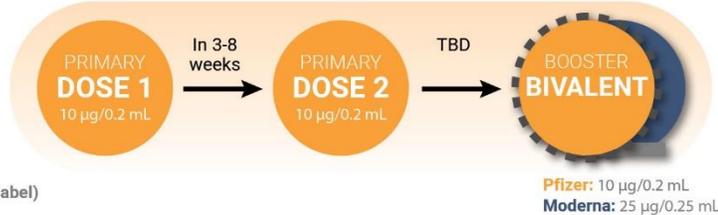
Primary/Booster Dose:
Pfizer Orange Cap



Pfizer-BioNTech Ages 6 years–11 years

dose/injection volume
(dilute before use)

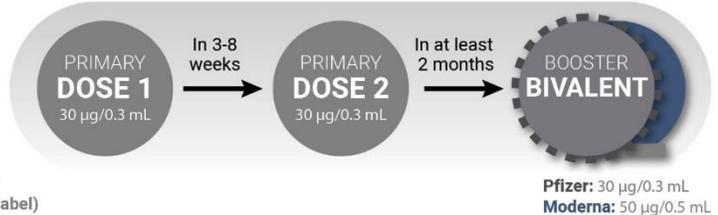
Primary Dose:
Pfizer Orange Cap
Bivalent Booster:
Pfizer Orange Cap
Moderna Dark Blue Cap (gray label)



Pfizer-BioNTech Ages 12 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.

***Example:
Pending
Authorization***

* 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.

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Pfizer For Moderately to Severely Immunocompromised Populations

Pfizer-BioNTech Ages 6 months–4 years

dose/injection volume
(dilute before use)

Primary Dose:
Maroon Cap



Pfizer-BioNTech 5 year olds ONLY

dose/injection volume
(dilute before use)

Primary/Booster Dose:
Pfizer Orange Cap



Pfizer-BioNTech Ages 6 years–11 years

dose/injection volume
(dilute before use)

Primary Dose:
Pfizer Orange Cap
Bivalent Booster:
Pfizer Orange Cap
Moderna Dark Blue Cap (gray label)



Pfizer: 10 µg/0.2 mL
Moderna: 25 µg/0.25 mL

Pfizer-BioNTech Ages 12 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)



Pfizer: 30 µg/0.3 mL
Moderna: 50 µg/0.5 mL

**Example:
*Pending
Authorization***

* 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.

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Moderna

Moderna Ages 6 months–4 years

dose/injection volume
(Do NOT dilute before use)

Primary Dose:
Blue Cap (magenta label)



Moderna 5 year olds ONLY

dose/injection volume
(Do NOT dilute before use)

Primary Dose:
Blue Cap (magenta label)

Bivalent Booster:
Pfizer Orange Cap



Moderna Ages 6 years–11 years

dose/injection volume
(Do NOT dilute before use)

Primary Dose:
Blue Cap (purple label)

Bivalent Booster:
Moderna Dark Blue Cap (gray label) or
Pfizer Orange Cap



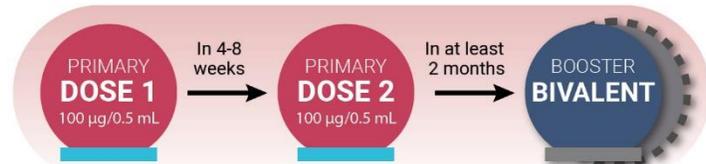
Moderna: 25 µg/0.2 mL
Pfizer: 10 µg/0.2 mL

Moderna Ages 12 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)



Moderna: 50 µg/0.5 mL
Pfizer: 30 µg/0.3 mL



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

Example:
Pending Authorization

* 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 For Moderately to Severely Immunocompromised Populations

Moderna Ages 6 months–4 years

dose/injection volume
(Do NOT dilute before use)

Primary Dose:
Blue Cap (magenta label)



Moderna 5 year olds ONLY

dose/injection volume
(Do NOT dilute before use)

Primary Dose:
Blue Cap (magenta label)
Bivalent Booster:
Pfizer Orange Cap



Moderna Ages 6 years–11 years

dose/injection volume
(Do NOT dilute before use)

Primary Dose:
Blue Cap (purple label)
Bivalent Booster:
Moderna Dark Blue Cap (gray label) or
Pfizer Orange Cap



Moderna Ages 12 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)



Example:
*Pending
Authorization*

* 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.

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‡ 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](#).

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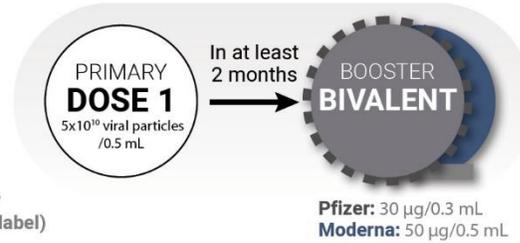
Janssen and Novavax

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)



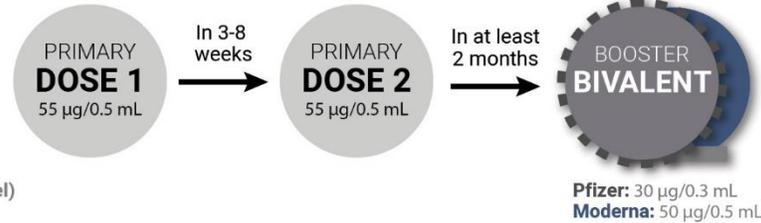
▶ All charts are available at illinoisvaccinates.com/resources

Novavax Ages 12 years and older

dose/injection volume

Bivalent Boosters:

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



Example:
*Pending
Authorization*



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!**



Reminders

- ▷ 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.



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?

▷ Currently: Yes.

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.



FAQs

Can other vaccines be given with bivalent boosters?

▷ YES!

COVID-19 vaccines may be administered without regard to timing of other vaccines. This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day.

There are additional considerations if administering an orthopoxvirus vaccine (see CDC guidance).



Talking to Parents and Caregivers

Why do we need an updated boosters?

For more protection from COVID-19. Each booster helps to give longer protection. The COVID-19 virus has changed since the vaccines first came out and we now have the Omicron strain. A bivalent vaccine will provide even more protection against current and future strains of the virus related to Omicron.

Why should my child get an updated booster?

Cases are probably going to increase this winter due to more time spent inside and fewer masking requirements. The virus is continuously changing and we have to change with it! Staying up to date with vaccines is the best way to avoid hospitalization, death, and other long term health conditions that we know COVID-19 can and does cause.





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.



Upcoming Trainings and Support

ADVISOR OFFICE HOURS		
Tuesday	October 4	12 pm–1 pm
Friday	October 14	12 pm–1 pm
Thursday	October 20	12 pm–1 pm
Tuesday	October 25	12 pm–1 pm

- ▷ **I-VAC Office Hours**
 - ▷ Follow [this link](#) to join on Zoom
- ▷ **Learning Collaborative sessions, held bi-weekly**
 - Pediatric sessions** begin Tuesday, October 11th
5:30pm to 6:30pm
&
 - Adult sessions** begin Wednesday, October 19th
5:30pm to 6:30pm
- ▷ **Moderna**
 - ▷ Trainings [link](#)
 - ▷ Office hours and regional contacts [link](#)
- ▷ **Pfizer**
 - ▷ Trainings [link](#)



Additional Resources + Outreach Materials

- ▷ 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
 - ▷ Pediatrics COVID-19 Vaccines – [English](#), [Spanish](#)
 - ▷ **Updated** COVID-19 Boosters – [English](#), [Spanish](#)
 - ▷ **NEW** Pediatric **updated** COVID-19 Boosters – [English](#), [Spanish](#)
- ▷ AAP dosing guide for when a child has birthdays in between doses [here](#)
- ▷ Pfizer trainings [here](#)
- ▷ Fall bivalent boosters: Science update from YLE [here](#)



COVID-19 VACCINE BOOTCAMP

✓ gain knowledge

A lot has changed in terms of eligibility and clinical guidance around COVID-19 vaccines. It is important now more than ever to ensure your facility and staff are up to date on COVID-19 information. Practice skills through activities.

✓ connect with peers

While gaining skills related to COVID-19 vaccine administration and distribution. Learn strategies for overcoming vaccine hesitancy through culturally and linguistically appropriate methods.

✓ get free CME/CE

 The Illinois Chapter, American Academy of Pediatrics is accredited by the Illinois State Medical Society (ISMS) to provide continuing medical education for physicians.

The Illinois Chapter, American Academy of Pediatrics designates each live training for a maximum of 4 AMA PRA Category 1 Credit(s)[™]. Physicians should claim only the credit commensurate with the extent of their participation in the activity. Nurses and Nurse Practitioners can submit Certificates of Attendance to their accrediting board to claim credit for participation in the live webinars.

THURSDAY
NOVEMBER 3, 2022

MALCOLM X COLLEGE

**1900 W JACKSON BLVD,
CHICAGO, IL 60612**

9AM TO 2PM

BREAKFAST AND LUNCH INCLUDED

Registration information coming soon



Contact Information

IDPH

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

CDPH

- ▷ Kevin Hansen: Kevin.Hansen@cityofchicago.org
- ▷ COVID19vaccine@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

- ▷ 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
- ▷ 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
- ▷ Chatbot [here](#)



Thank You

▷ Stay tuned.

It is anticipated that at least one bivalent vaccine for children aged 6 months to 4 years may be authorized later in the fall.

Keep this and storage space in mind when developing your overall fall vaccine plans.