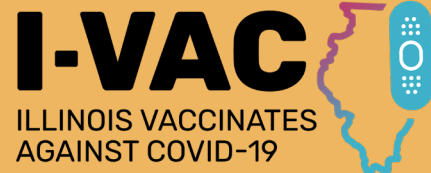


Simplified COVID-19

Schedules & More

Tuesday, April 25, 2023

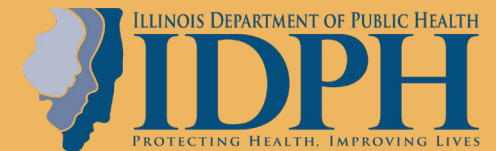


Illinois Chapter

INCORPORATED IN ILLINOIS

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®



Agenda

- ▷ **New Schedules by Age Group** – Illinois Chapter, American Academy of Pediatrics (ICAAP) and Illinois Vaccinates Against COVID-19 (I-VAC): Daniel Johnson, MD, FAAP
- ▷ **Product Expirations and Ordering** – Chicago Department of Public Health: Kevin Hansen and Illinois Department of Public Health: Karyn Lyons, MS, RN
- ▷ **What We Know About Commercialization** – Illinois Vaccinates Against COVID-19 (I-VAC): Jennifer Burns, APN
- ▷ **Q & A Session** – Moderated by ICAAP: Caroline Werenskjold, MPH

The State of COVID-19

— Wastewater — Clinical cases daily avg █ Clinical daily cases

☒ Show cases

Total results

Last 6 months

Last 6 weeks

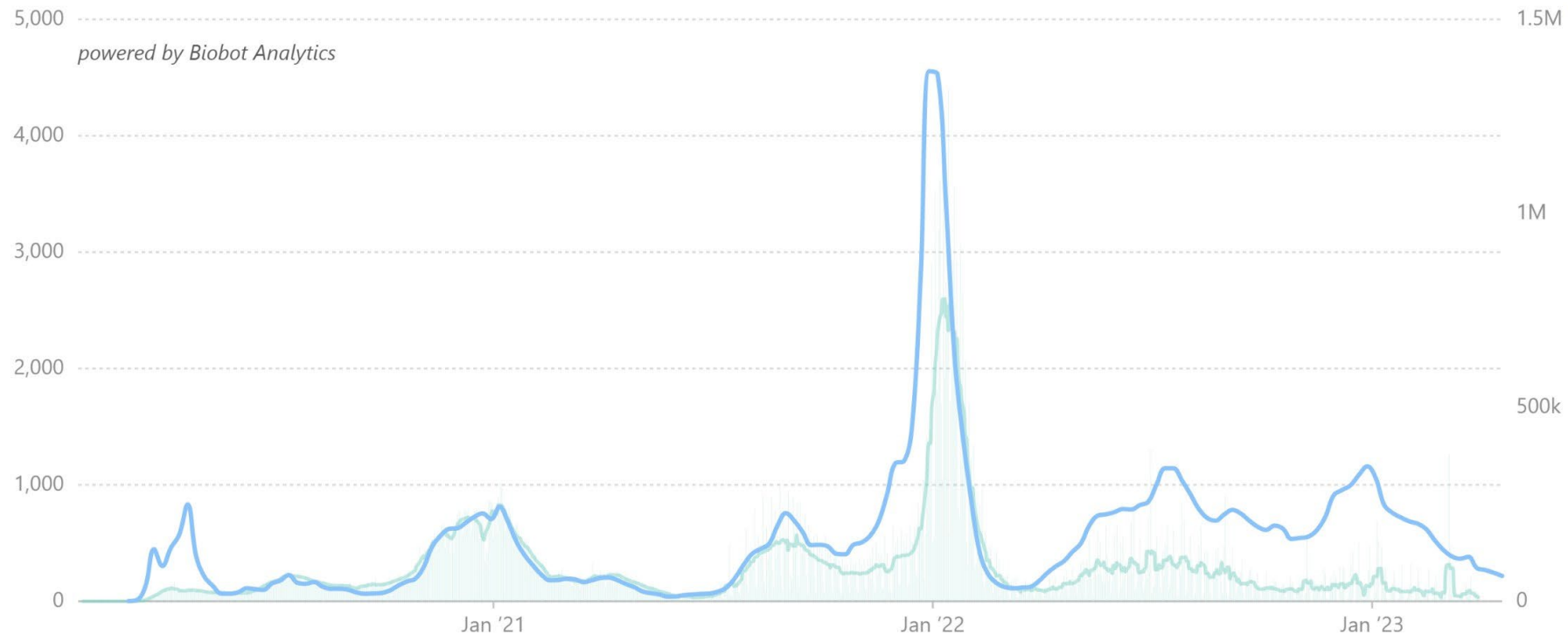
Wastewater:
Effective SARS-
CoV-2 virus
concentration
(copies / mL of
sewage)

5,000
4,000
3,000
2,000
1,000
0

powered by Biobot Analytics

Clinical:
Daily new cases

1.5M
1M
500k
0



Source: Wastewater data from Biobot Analytics; Clinical data from [USAFacts](#)

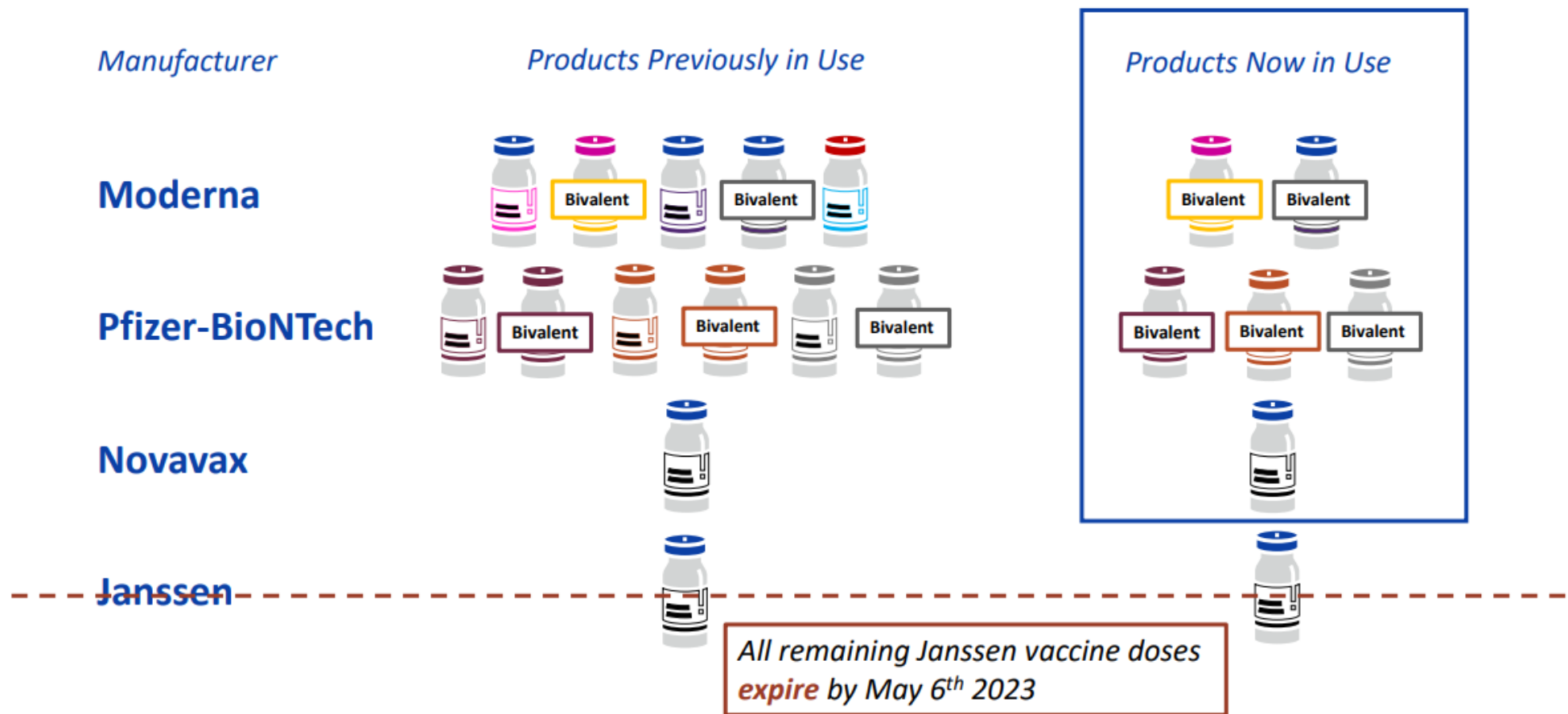


Hooray!

A simplified schedule is here...sort of.

Not for children.

Products in Use





How We Got Here



4.18.23

FDA Amended EUAs

Of the Moderna and Pfizer-BioNTech COVID-19 bivalent mRNA vaccines.

[Moderna](#)
[Pfizer](#)



4.19.23

ACIP Met

Discussed vaccine data and schedules. No votes.



4.19.23

CDC Endorsed Support

It is all happening.

Bivalent Vaccines

CDC presented data that shows:

- Bivalent vaccines are safe.
- Effectiveness: Waning against hospitalization.
- Efficacy for bivalent vaccines among those over 65 years decreased from 64% to 39%.

AGES 6 MONTHS TO <5 YEARS

Additional Considerations

An 8-week interval between the first and second doses of Moderna and Pfizer-BioNTech COVID-19 vaccines might be optimal for some people ages 6 months–64 years, especially for males ages 12–39 years, as data suggests it reduces the small risk of myocarditis and pericarditis associated with these vaccines.

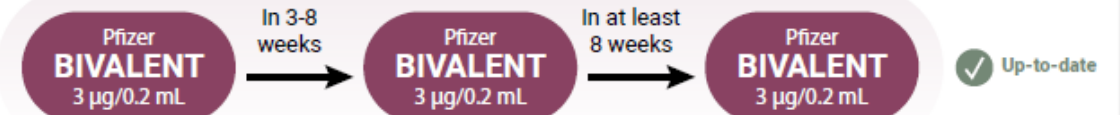
UNVACCINATED

dose/injection volume

Moderna Bivalent:
(Do NOT dilute before use)
Dark Blue Cap (gray label)

Pfizer Bivalent:
(dilute before use)
Maroon Cap

OR



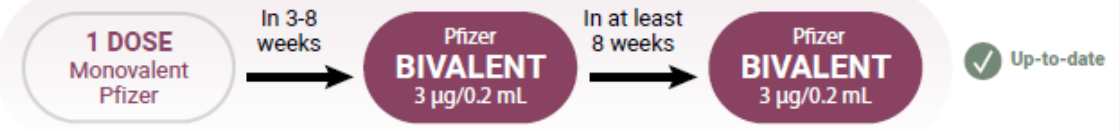
PREVIOUSLY VACCINATED

dose/injection volume

○ Previously Received COVID-19 Vaccines

Moderna Bivalent:
(Do NOT dilute before use)
Dark Blue Cap (gray label)
Dark Pink Cap (yellow label)

Pfizer Bivalent:
(dilute before use)
Maroon Cap



AGES 6 MONTHS TO <5 YEARS - MODERATELY TO SEVERELY IMMUNOCOMPROMISED

For Pfizer, there is no new additional guidance for immunocompromised at this time.

For Moderna for the unvaccinated, give an extra dose as indicated in the chart.

Certain kinds of immunocompromise refers to individuals who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

UNVACCINATED


dose/injection volume

Moderna Bivalent:
(Do NOT dilute before use)
Dark Blue Cap (gray label)

Pfizer Bivalent:
(dilute before use)
Maroon Cap

PREVIOUSLY VACCINATED

dose/injection volume

 Previously Received
COVID-19 Vaccines

Moderna Bivalent:
(Do NOT dilute before use)
Dark Blue Cap (gray label)
Dark Pink Cap (yellow label)

Pfizer Bivalent:
(dilute before use)
Maroon Cap



AGES 5 TO <6 YEARS

UNVACCINATED

dose/injection volume

Moderna Bivalent:
(Do NOT dilute before use)
Dark Blue Cap (gray label)

Pfizer Bivalent:
(dilute before use)
Orange Cap

OR

Moderna
BIVALENT
25 µg/0.25 mL

In 4-8
weeks

Moderna
BIVALENT
25 µg/0.25 mL

✓ Up-to-date

Pfizer
BIVALENT
10 µg/0.2 mL

✓ Up-to-date

PREVIOUSLY VACCINATED

dose/injection volume

☐ Previously Received
COVID-19 Vaccines

Moderna Bivalent:
(Do NOT dilute before use)
Dark Blue Cap (gray label)
Dark Pink Cap (yellow label)

Pfizer Bivalent:
(dilute before use)
Orange Cap

1 DOSE
Monovalent
Moderna

In 4-8
weeks

Moderna
BIVALENT
25 µg/0.25 mL

OR

In at least
8 weeks

Pfizer
BIVALENT
10 µg/0.2 mL

✓ Up-to-date

2 DOSES
Monovalent
Moderna

In at least
8 weeks

Moderna
BIVALENT
10 µg/0.2 mL

OR

In at least
8 weeks

Pfizer
BIVALENT
10 µg/0.2 mL

✓ Up-to-date

2 DOSES
Monovalent
Moderna

→

Moderna or Pfizer
BIVALENT

✓ Up-to-date

1 or 2 DOSES
Monovalent
Pfizer

In at least
8 weeks

Pfizer
BIVALENT
10 µg/0.2 mL

✓ Up-to-date

2 DOSES
Monovalent
Pfizer

→

Pfizer
BIVALENT

✓ Up-to-date

Pfizer
BIVALENT

✓ Up-to-date

AGES 5 TO <6 YEARS IMMUNOCOMPROMISED

Immunocompromised Guidance for Pfizer-BioNTech

For individuals with certain kinds of immunocompromise 5 years of age and older, a single additional age-appropriate dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent may be administered at least 2 months following the initial dose of a bivalent COVID-19 vaccine; additional age-appropriate doses of Pfizer- BioNTech COVID-19 Vaccine, Bivalent may be administered at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances.

Immunocompromised Guidance for Moderna

For individuals with certain kinds of immunocompromise 5 to <6 years of age who have received two 0.25 mL doses (Moderna COVID-19 Vaccine or Moderna COVID-19 Vaccine, Bivalent), an additional 0.25 mL dose of Moderna COVID-19 Vaccine, Bivalent (vial with a dark blue cap and a label with a gray border) may be administered at least 1 month following the most recent dose; additional doses of Moderna COVID-19 Vaccine, Bivalent may be administered at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances.

AGES 6 TO <12 YEARS

UNVACCINATED

dose/injection volume

Moderna Bivalent:
(Do NOT dilute before use)
Dark Blue Cap (gray label)

Pfizer Bivalent:
(dilute before use)
Orange Cap



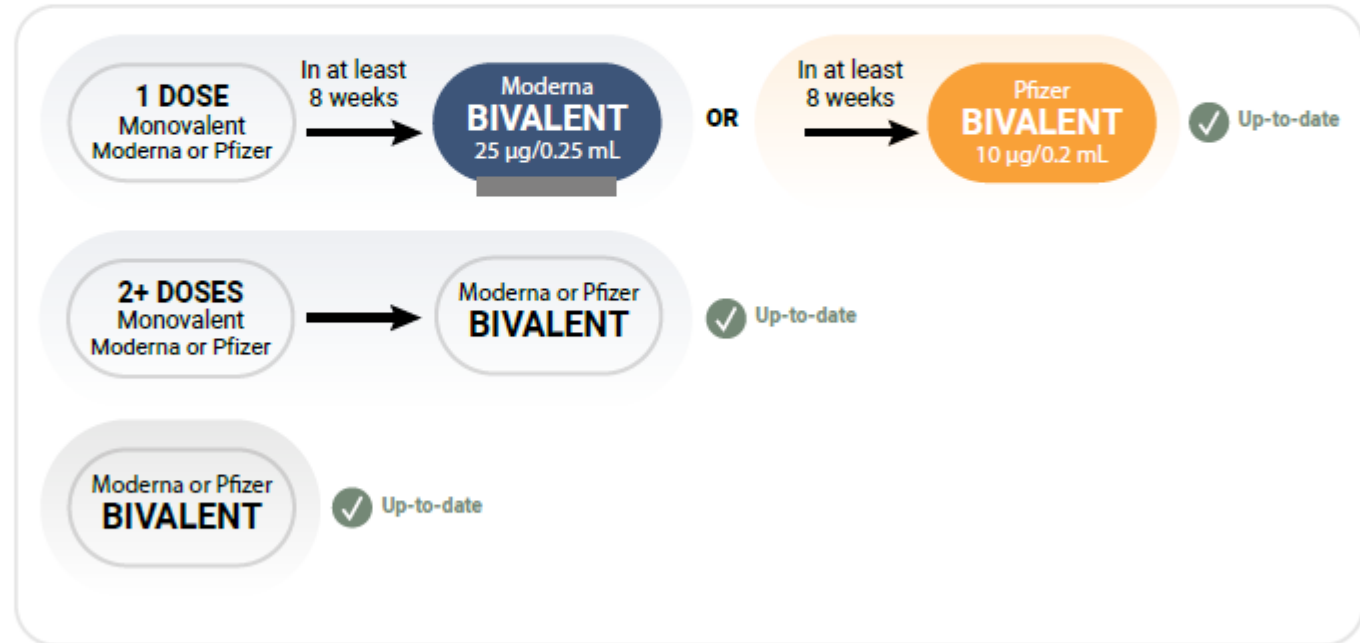
PREVIOUSLY VACCINATED

dose/injection volume

☐ Previously Received
COVID-19 Vaccines

Moderna Bivalent:
(Do NOT dilute before use)
Dark Blue Cap (gray label)
Dark Pink Cap (yellow label)

Pfizer Bivalent:
(dilute before use)
Orange Cap



AGES 6 TO <12 YEARS IMMUNOCOMPROMISED

Immunocompromised Guidance for Pfizer-BioNTech

For individuals with certain kinds of immunocompromise 5 years of age and older, a single additional age-appropriate dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent may be administered at least 2 months following the initial dose of a bivalent COVID-19 vaccine; additional age-appropriate doses of Pfizer- BioNTech COVID-19 Vaccine, Bivalent may be administered at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances.

Immunocompromised Guidance for Moderna

For individuals with certain kinds of immunocompromise 6 years and older who have received one 0.25 mL doses (Moderna COVID-19 Vaccine or Moderna COVID-19 Vaccine, Bivalent), an additional 0.25 mL dose of Moderna COVID-19 Vaccine, Bivalent (vial with a dark blue cap and a label with a gray border) may be administered at least 1 month following the most recent dose; additional doses of Moderna COVID-19 Vaccine, Bivalent may be administered at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances.

AGES 12 YEARS AND OLDER

UNVACCINATED

dose/injection volume

Moderna Bivalent:
(Do NOT dilute before use)
Dark Blue Cap (gray label)

Pfizer Bivalent:
(Do NOT dilute before use)
Gray Cap

OR

Moderna
BIVALENT
50 µg/0.5 mL

✓ Up-to-date

Pfizer
BIVALENT
30 µg/0.3 mL

✓ Up-to-date

PREVIOUSLY VACCINATED

dose/injection volume

☐ Previously Received
COVID-19 Vaccines

Moderna Bivalent:
(Do NOT dilute before use)
Dark Blue Cap (gray label)

Pfizer Bivalent:
(Do NOT dilute before use)
Gray Cap

1+ DOSES
Monovalent
Moderna or Pfizer

In at least
8 weeks

Moderna
BIVALENT
50 µg/0.5 mL

OR

In at least
8 weeks

Pfizer
BIVALENT
30 µg/0.3 mL

✓ Up-to-date

Moderna or Pfizer
BIVALENT

✓ Up-to-date

ADDITIONAL DOSES

dose/injection volume

☐ Previously Received
COVID-19 Vaccines

Moderna Bivalent:
(Do NOT dilute before use)
Dark Blue Cap (gray label)

Pfizer Bivalent:
(Do NOT dilute before use)
Gray Cap

65 YEARS AND OLDER

People ages 65 years and older have the option to receive 1 additional bivalent mRNA vaccine dose at least 4 months after the first dose of a bivalent mRNA vaccine.

Moderna or Pfizer
BIVALENT

In at least
4 months

Moderna
BIVALENT
50 µg/0.5 mL

OR

In at least
4 months

Pfizer
BIVALENT
30 µg/0.3 mL

✓ Up-to-date

AGES 12 YEARS AND OLDER

Immunocompromised Guidance for Pfizer-BioNTech

For individuals with certain kinds of immunocompromise 5 years of age and older, a single additional age-appropriate dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent may be administered at least 2 months following the initial dose of a bivalent COVID-19 vaccine; additional age-appropriate doses of Pfizer- BioNTech COVID-19 Vaccine, Bivalent may be administered at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances.

Immunocompromised Guidance for Moderna

For individuals with certain kinds of immunocompromise 6 years and older who have received one 0.25 mL doses (Moderna COVID-19 Vaccine or Moderna COVID-19 Vaccine, Bivalent), an additional 0.25 mL dose of Moderna COVID-19 Vaccine, Bivalent (vial with a dark blue cap and a label with a gray border) may be administered at least 1 month following the most recent dose; additional doses of Moderna COVID-19 Vaccine, Bivalent may be administered at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances.

Monovalent mRNA Vaccines

- ▷ No longer authorized.
- ▷ Should be **immediately removed from inventory**.
 - ▷ You should waste them in I-CARE and mark them out of stock.
- ▷ **All monovalent Moderna and Pfizer-BioNTech mRNA vaccines** should be disposed of in medical waste containers.
 - ▷ Medical waste disposal requirements may vary by jurisdiction.

Questions

If a deauthorized vaccine is inadvertently administered?

- ▶ Review Interim Clinical Considerations for Use of COVID-19 Vaccines.
- ▶ Report vaccine administration errors to the Vaccine Adverse Event Reporting System (VAERS).

Questions

What about people who received Novavax or Janssen vaccines as their primary series?

- ▷ No new information provided.
- ▷ People ages 18 years and older who completed primary vaccination and have **not** received any previous booster dose(s) (including any previous monovalent or bivalent mRNA booster dose[s]) may receive a monovalent Novavax booster dose at least 6 months after completion of the primary series if they are unable to receive an mRNA vaccine (i.e., mRNA vaccine contraindicated or not available) or unwilling to receive an mRNA vaccine and would otherwise not receive a booster dose.

Questions

What if someone just had COVID-19?

- ▶ No new update based on infection history.

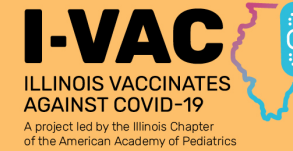
Questions

What about pregnant people?

- ▷ Eligible for *one* bivalent booster.

STORAGE & HANDLING

MODERNA STORAGE & HANDLING INFORMATION

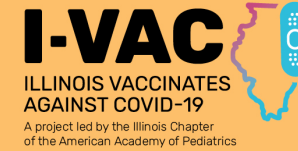


| AGE INDICATIONS AND FORMULATION | 6 months through 5 years (Bivalent) | 6 months and older (Bivalent) |
|--------------------------------------------------------|-------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| VIAL CAP COLOR | Dark Pink | Dark Blue |
| VIAL LABEL BORDER COLOR | Yellow | Gray |
| PREPARATION | Do Not Dilute | Do Not Dilute |
| DOSE VOLUME/DOSE | 0.2 mL/10 mcg | <ul style="list-style-type: none"> • 6 months to 5 years old: 0.25 mL/25 mcg • 6 to 11 years old: 0.25 mL/25 mcg • 12 years and older: 0.5 mL/50 mcg |
| DOSES PER VIAL | 2 doses | Varies by age |
| 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 8 hours | 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.

STORAGE & HANDLING

PFIZER-BIONTECH STORAGE & HANDLING INFORMATION

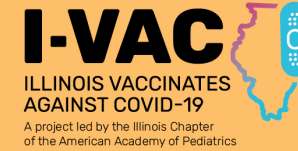


| AGE INDICATIONS | 6 months through 4 years | 5 years through 11 years | 12 years and older |
|-----------------------------------------------------------|----------------------------------|------------------------------|-------------------------|
| FORMULATION | Bivalent | Bivalent | Bivalent |
| VIAL CAP COLOR/LABEL WITH COLOR BORDER | Maroon/ Bivalent label | Orange/ Bivalent label | Gray/ Bivalent label |
| PREPARATION | Dilute Before Use | Dilute Before Use | Do Not Dilute |
| AMOUNT OF DILUENT NEEDED PER VIAL ^a | 2.2 mL | 1.3 mL | |
| DOSE VOLUME/DOSE | 0.2mL/3mcg | 0.2 mL/10 mcg | 0.3 mL/30 mcg |
| DOSES PER VIAL | 10 doses (after dilution) | 10 doses (after dilution) | 6 doses or 1 dose |
| ULT FREEZER (-90°C TO -60°C) ^b | 18 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.

STORAGE & HANDLING

JANSSEN & NOVAVAX STORAGE & HANDLING INFORMATION



| | JANSSEN (Johnson & Johnson) | NOVAVAX |
|-----------------------------------------------------------|------------------------------------------------------------------------------|---------------------------------------------------|
| AGE INDICATIONS | 18 years and older | 12 years and older |
| FORMULATION | Primary Series and Booster Dose | Primary Series |
| VIAL CAP COLOR/ LABEL WITH COLOR BORDER | Blue Cap, White Label | Royal Blue Cap |
| PREPARATION | Do Not Dilute | Do Not Dilute |
| DOSE VOLUME/DOSE | 5 X10 ¹⁰ viral particles | 0.5mL / 5mcg rS and 50mcg of Matrix M adjuvant |
| DOSES PER VIAL | 5 primary doses or booster doses | 10 or 5 |
| ULT FREEZER (-90°C TO -60°C) | N/A | N/A |
| FREEZER (-25°C TO -15°C) | N/A | N/A |
| REFRIGERATOR (2°C TO 8°C) ^a | Up to 11 months | Until expiration date |
| ROOM TEMPERATURE (8°C TO 25°C) including any thaw time | 12 hours prior to first puncture | N/A |
| AFTER FIRST PUNCTURE (2°C TO 25°C) | Administer within 6 hours if refrigerated or within 2 at room temperature | 12 hours |

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

Ordering Quantities

Packing will continue to say “booster only” on some products

| | Pfizer | | | | Moderna | |
|------------------------|---------------------------------------------|------------------------------------------|-------------------------------------|-------------------------------------------------------------|--------------------------------|-----------------------|
| Formulation | 6 mos – 4 years Bivalent (maroon cap) | 5 – 11 years Bivalent (orange cap) | 12+ years Bivalent (gray cap) | 12+ years Bivalent Single-Dose Vials (gray cap) | 6 mos – 5 years Bivalent | 6+ months Bivalent |
| # vials per tray | 10 | 10 | 10 | 10 | 10 | 10 |
| # doses per tray | 100 | 100 | 60 | - | 20 | 50 |
| Minimum order quantity | 100 doses | 100 doses | 180 doses | 50 doses | 20 doses | 100 doses |
| Delivery time | ~1 week | | | | ~1 Week for Available Products | |

Janssen & Novavax

- ▷ J & J expire May 6, 2023
- ▷ 10 dose Novavax vials expire April 30, 2023
- ▷ 5 dose Novavax vials expire October 31, 2023

| | Janssen | Novavax |
|-------------------------------|-----------|----------------------------|
| Formulation | 18+ | 12+ |
| # vials per tray | 10 | 10 |
| # doses per tray | 100 | 50 |
| Minimum order quantity | 100 doses | 100 doses (2 trays) |
| Delivery time | ~1 week | |

End of Public Health Emergency (PHE) - Federal

- ▷ The federal PHE will end May 11, 2023.
- ▷ COVID-19 vaccines will still be available – EUAs will not be impacted.
- ▷ Insurance companies will no longer be required to cover the cost of COVID-19 tests.
- ▷ HHS will no longer be able to require reporting of COVID-19 test results.
- ▷ The end of the PHE is **not** tied to the commercialization of COVID-19 vaccines.

End COVID-19 Disaster Proclamation - Illinois

- ▷ Will end May 11, 2023.
- ▷ The proclamation allowed for...
 - ▷ Federal reimbursement for state response costs.
 - ▷ Use of State Disaster Relief Fund, covering direct state costs and reimbursements to Illinois National Guard and mutual aid groups.
 - ▷ Use of the state's mutual aid network, groups of public safety response professionals (health care providers and management professionals, law enforcement officers, fire fighters, emergency medical technicians, disaster response professionals) that are available to deploy to areas of shortage.
 - ▷ The activation of Illinois National Guard reservists, some of whom were doctors and nurses and served on the front lines of the pandemic response.
 - ▷ Additional executive actions as needed to protect public health and safety.

Future Vaccinators

- ▷ HHS announcement last week on [PREP Act and Pharmacy Administration of Vaccines](#)

Commercialization – Coming Fall 2023?

- ▷ The transition from direct government purchase to purchase by public and private payers.
- ▷ Vaccine costs will be covered by private/public insurance – how much is unknown.
 - ▷ Will be covered by Vaccines for Children (VFC) program.
- ▷ Upfront costs for providers who purchase COVID-19 vaccines – how much is unknown.

What is Next

Illinois Chapter

INCORPORATED IN ILLINOIS

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®



June 2023

The FDA meets to discuss
the fall vaccine plans
and the vaccine
variant formula.



**June 21-22
ACIP Meetings**



Keep Vaccinating

Messaging

- ▷ Those under 5 needs to get a primary series.
- ▷ Everyone who is not vaccinated should get vaccinated.
- ▷ Everyone should get a bivalent dose.
- ▷ Everyone who is immunocompromised should consider getting a second bivalent dose.
 - ▷ Work with your provider.
- ▷ Acceptable to give a second bivalent to anyone 65+ (provider determination).
- ▷ We anticipate a future recommendation for an annual COVID-19 vaccine.

Q & A

Please use the Q & A box only.

Contact Information & Resources

IDPH

- ▷ dph.vaccines@illinois.gov
- ▷ I-CARE: dph.immunizations@illinois.gov
- ▷ HL7: DPH.HL7ICARE@illinois.gov

CDPH

- ▷ ChicagoVFC@cityofchicago.org
- ▷ Kevin Hansen: Kevin.Hansen@cityofchicago.org
- ▷ COVID19vaccine@cityofchicago.org
- ▷ chicagohan.org/vfc
- ▷ chicagohan.org/covid-19-vaccine/provider

ICAAP/I-VAC

- ▷ Illinoisaap.org
- ▷ Illinois Vaccinates Against COVID-19
- ▷ Facts@ilvaccinates.com

Additional Resources:

- ▷ [Updates to Interim Clinical Considerations for Use of COVID-19 Vaccines](#)
- ▷ [HHS COVID-19 Vaccine Planning Guide Spring/Summer 2023](#)
- ▷ [Presentation: Updates to COVID-19 vaccine policy: Considerations for Future Planning \(ACIP\)](#)
- ▷ [Moderna COVID-19 Vaccines \(FDA\)](#)
- ▷ [Pfizer COVID-19 Vaccines \(FDA\)](#)
- ▷ [Fact Sheet: HHS Announces Intent to Amend the Declaration Under the PREP Act for Medical Countermeasures Against COVID-19](#)

Upcoming Events

▷ **Illinois Vaccinates Against COVID-19 (I-VAC) Learning Collaborative – Pediatric Populations**

▷ Tuesday May 2nd, 5:30 – 6:30PM

▷ **Preparing for Summer Vacations – Travel Vaccinations**

▷ Tuesday May 16th, 12:00PM – 1:00PM

▷ **I-VAC Vaccine Bootcamp – In Person**

▷ Friday June 16th, 8:30AM – 2:00PM

▷ **Back to School, Back to Vaccine Basics – National Immunization Awareness Month**

▷ Tuesday June 20th, 12:00PM – 1:00PM

Register at illinoisaap.org/events



Manufacturer Office Hours

Novavax Office Hours

- ▶ Use this [link](#) to register
 - ▶ Tuesday, April 25 @ 2:00PM CDT
 - ▶ Wednesday, May 3 @ 1:00PM CDT

Moderna Office Hours

- ▶ Use this [link](#) to register – office hours available through Tuesday April 25th – Friday May 5th:
 - ▶ Tuesday, April 25 @ 1:00PM CDT
 - ▶ Wednesday, April 26 @ 11:00AM CDT & 1:00PM CDT

Pfizer Office Hours

- ▶ Use this [link](#) to register – office hours available through Tuesday April 25th – Thursday May 11th:
 - ▶ Tuesday, April 25 @ 2:00PM CDT
 - ▶ Wednesday, April 26 @ 11:00AM CDT