

Monthly Healthcare Provider & Public Health Partner Webinar

Updates on COVID-19, Monkeypox, & Other Emerging Public Health Issues

September 8, 2022

Updated COVID-19 Vaccine Recommendations


Bivalent Omicron (BA.4/BA.5) Booster Vaccines


Bivalent COVID-19 Booster Vaccine Recommendations

- All persons 12 years of age or older who have completed at least a COVID-19 vaccine primary series is recommended to receive a single bivalent vaccine booster (regardless of the number of prior booster shots with monovalent COVID-19 vaccines)
 - Pfizer-BioNTech Bivalent: Boosters for persons aged **12+ years**
 - Moderna Bivalent: Boosters for persons aged **18+ years**
- Bivalent booster vaccines contain spike protein mRNA for the original (ancestral/wild type) and Omicron BA.4/BA.5 virus strains

Monovalent vs. Bivalent COVID-19 Boosters


Current (Monovalent) COVID-19 vaccines


50µg  Moderna COVID-19 vaccine
50µg of spike protein from
'ancestral' ('original') SARS-CoV-2

30µg  Pfizer-BioNTech COVID-19 vaccine
30µg of spike protein from
'ancestral' ('original') SARS-CoV-2




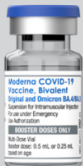




Bivalent vaccines have the
same total antigen amount
as monovalent vaccines

Updated (Bivalent) COVID-19 vaccines

50µg  Moderna COVID-19 vaccine
25µg of spike protein from
'ancestral' ('original') SARS-CoV-2
25µg of spike protein from
Omicron (BA.4/BA.5) SARS-CoV-2

30µg  Pfizer-BioNTech COVID-19 vaccine
15µg of spike protein from
'ancestral' ('original') SARS-CoV-2
15µg of spike protein from
Omicron (BA.4/BA.5) SARS-CoV-2

Moderna COVID-19 Vaccine Presentations

	Moderna COVID-19 Vaccine Primary Series (12 years of age and older)	Moderna COVID-19 Vaccine Primary Series* (6 through 11 years of age)	Moderna COVID-19 Vaccine Primary Series (6 months through 5 years of age)	Moderna COVID-19 Vaccine, Bivalent Booster Dose (18 years of age and older)
Dose Per Vial	Primary Series Doses only: maximum of 11 doses (range: 10-11 doses)	Primary Series Doses: 5 doses	Primary Series Doses: 10 doses	Bivalent Booster Dose: 5 doses
Dose Volume	Primary Series Dose: Each 0.5 mL	Primary Series Dose: Each 0.5 mL	Primary Series Dose: Each 0.25 mL	Bivalent Booster Dose: Each 0.5 mL
Vial Label	 Blue border NDC 80777-273-10	 Purple border NDC 80777-275-05	 Magenta border NDC 80777-279-05	 Gray border NDC 80777-282-05
Carton	 Blue border NDC 80777-273-99	 Purple border NDC 80777-275-99	 Magenta border NDC 80777-279-99	 Gray border NDC 80777-282-99

*The Moderna COVID-19 Vaccine vial labeled "BOOSTER DOSES ONLY" is authorized to provide Primary Series Doses (0.5 mL each) for individuals 6 through 11 years of age. Please see the "Dear HCP" Letter for more information at <https://eua.modernatx.com/covid19vaccine-eua/providers>

Pfizer-BioNTech COVID-19 Vaccine Presentations

**6 MONTHS THROUGH
4 YEARS OF AGE,
DILUTE BEFORE USE**



Maroon Cap¹

DOSE
3 mcg

DOSE VOLUME
0.2 mL

AMOUNT OF DILUENT NEEDED
PER VIAL[†]
2.2 mL

DOSES PER VIAL
10 doses per vial (after dilution)

REFRIGERATED STORAGE TIME
10 weeks

**5 THROUGH
11 YEARS OF AGE,
DILUTE BEFORE USE**



Orange Cap²

DOSE
10 mcg

DOSE VOLUME
0.2 mL

AMOUNT OF DILUENT NEEDED
PER VIAL[†]
1.3 mL

DOSES PER VIAL
10 doses per vial (after dilution)

REFRIGERATED STORAGE TIME
10 weeks

**12 YEARS OF AGE
AND OLDER,
DO NOT DILUTE**



Gray Cap³

DOSE
30 mcg

DOSE VOLUME
0.3 mL

AMOUNT OF DILUENT NEEDED
PER VIAL[†]
NO DILUTION

DOSES PER VIAL
6 doses per vial

REFRIGERATED STORAGE TIME
10 weeks

**12 YEARS OF AGE
AND OLDER,
DILUTE BEFORE USE**



Purple Cap⁴

DOSE
30 mcg


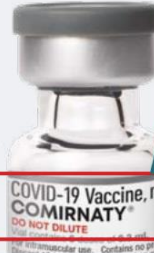

DOSE VOLUME
0.3 mL

AMOUNT OF DILUENT NEEDED
PER VIAL[†]
1.8 mL

DOSES PER VIAL
6 doses per vial (after dilution)

REFRIGERATED STORAGE TIME
1 month

Pfizer-BioNTech Gray-Cap Vials

	PRIMARY SERIES		BOOSTER DOSE ONLY
Name	Pfizer-BioNTech COVID-19 Vaccine DO NOT DILUTE	COMIRNATY® (COVID-19 Vaccine, mRNA) DO NOT DILUTE	Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) DO NOT DILUTE
Variant Composition	Monovalent: 30 mcg modRNA-Original ["Monovalent" refers to vaccine that encodes the spike protein of only the Original SARS-CoV-2]		Bivalent: 15 mcg modRNA-Original and 15 mcg modRNA-Omicron BA.4/BA.5
Authorized Use (AU) or Indication	Primary Series AU: as a 2-dose primary series to individuals 12 years of age and older; and a third primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise*	Primary Series AU: as a third primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise* Primary Series Indication: as a 2-dose primary series to individuals 12 years of age and older	Bivalent AU: for 12 years of age and older as a single booster dose administered at least 2 months after: <ul style="list-style-type: none"> • completion of primary vaccination with any authorized or approved monovalent COVID-19 vaccine, or • receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine
Cap Color & Label <i>Gray caps and labels with gray borders</i>	 Pfizer-BioNTech COVID-19 Vaccine NDC number: 59267-1025-1 Multiple Dose Vial: 59267-1025-1	 COMIRNATY® (COVID-19 Vaccine, mRNA) NDC number: 0089-2025-01 Multiple Dose Vial: 0089-2025-01	 Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) NDC number: 59267-0304-1 Multiple Dose Vial: 59267-0304-1

Pfizer-BioNTech COVID-19 Vaccine, Bivalent has the same storage, handling, preparation, dose volume, and administration instructions as Pfizer-BioNTech COVID-19 Vaccine gray cap vials and COMIRNATY gray cap vials, all of which MUST NOT BE DILUTED.

Additional Important Clarifications

- Bivalent booster vaccines can **ONLY** be used for booster doses and **NOT** primary series vaccination
- Bivalent vaccines can only be used currently as booster shots in persons 12+ years of age
- Original monovalent vaccines can **NO LONGER** be used as booster doses in persons 12+ years of age
- Children 5-11 years of age who qualify for a booster dose (i.e., those vaccinated with a Pfizer-BioNTech primary series) can only receive the Pfizer-BioNTech monovalent vaccine for a booster
- Original monovalent vaccines still are needed for primary series vaccination

Timing of Bivalent Booster Vaccination

- CDC recommends the updated bivalent vaccine boosters be administered *at least* 2 months after completion of the primary series, or *at least* 2 months after the last monovalent booster
- NH DPHS suggest waiting *at least* 3 months since prior vaccination or SARS-CoV-2 infection before administering the bivalent booster to maximize immune protection and minimize side effects
 - Timing is ultimately dependent on a person's COVID-19 risk, including immunocompromised status
 - Anybody infected with SARS-CoV-2 in the last few months would have been infected with either the BA.2, BA.4, or BA.5 Omicron sub-variants, which will provide protection against currently circulating variants
 - Monovalent vaccine protection against severe disease doesn't decrease quickly over 2 months
 - Clinical trials studied bivalent booster vaccination at least 3 months after prior dose, and people with a history of infection in the prior 3 months were excluded from study

Fall Booster “Reset”

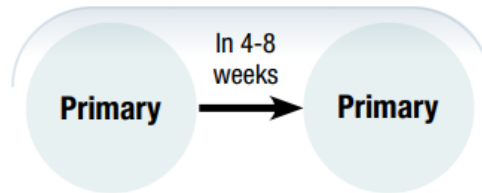
- Recommendations are simplified
- Change from dose counting to 1 bivalent booster for everyone eligible
- If eligible, a bivalent should not be denied based on total number of doses

Vaccination history	→	Next dose
Primary series	At least 2 months →	1 bivalent booster dose
Primary series + 1 booster	At least 2 months →	1 bivalent booster dose
Primary series + 2 booster	At least 2 months →	1 bivalent booster dose

COVID-19 Vaccination for People NOT Moderately-Severely Immunocompromised

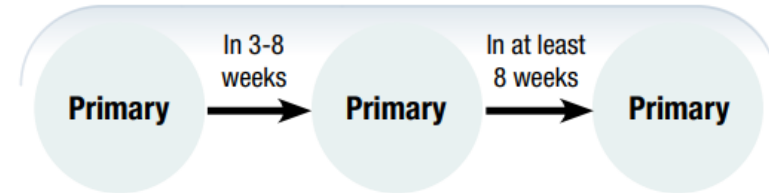
People ages 6 months through 4 years

Moderna



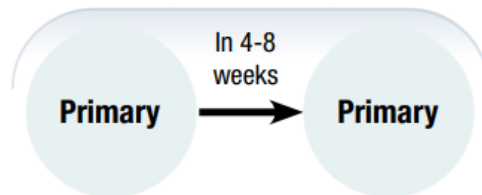
-OR-

Pfizer-BioNTech



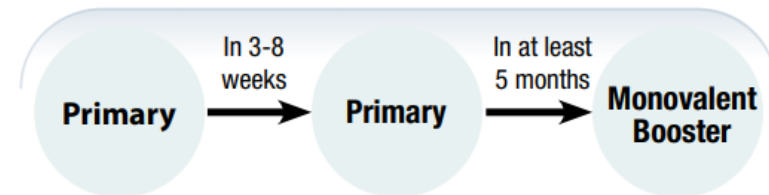
People ages 5 through 11 years

Moderna



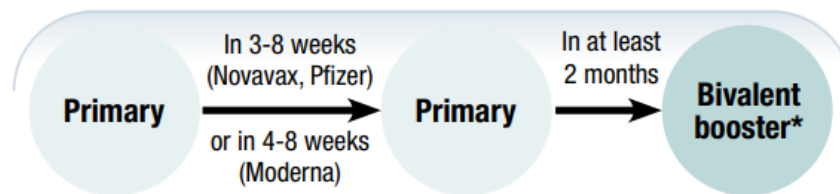
-OR-

Pfizer-BioNTech

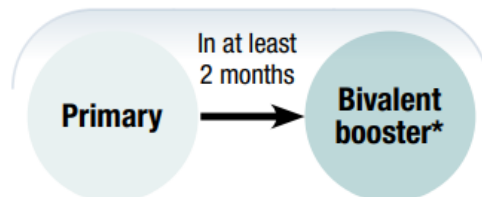


People ages 12 years and older

Moderna, Novavax, or Pfizer-BioNTech



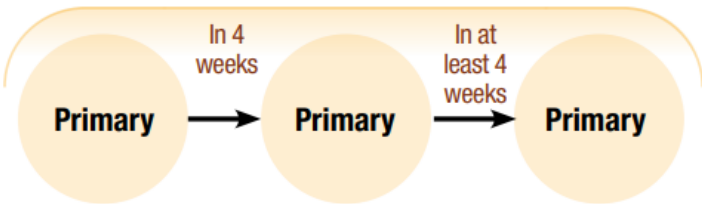
People ages 18 years and older who previously received Janssen primary series dose[†]



COVID-19 Vaccination for People Who ARE Moderately-Severely Immunocompromised

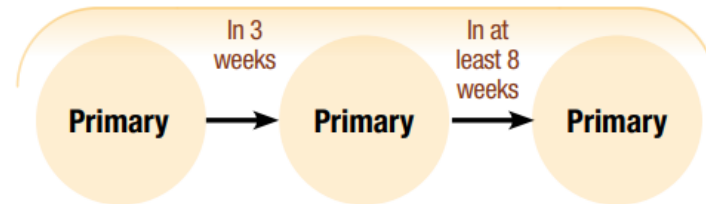
People ages 6 months through 4 years

Moderna



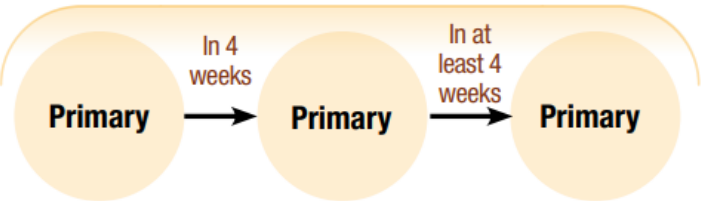
-OR-

Pfizer-BioNTech



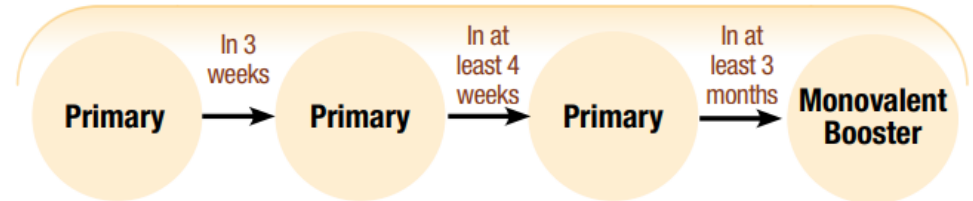
People ages 5 years through 11 years

Moderna



-OR-

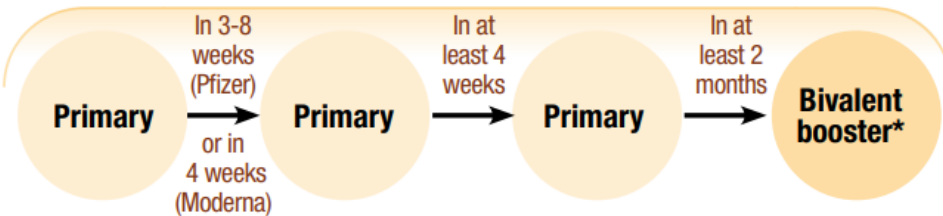
Pfizer-BioNTech



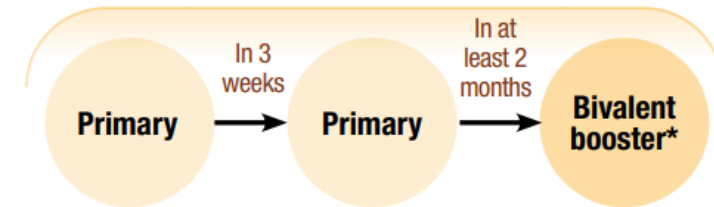
COVID-19 Vaccination for People Who ARE Moderately-Severely Immunocompromised

People ages 12 years and older

Moderna or Pfizer-BioNTech

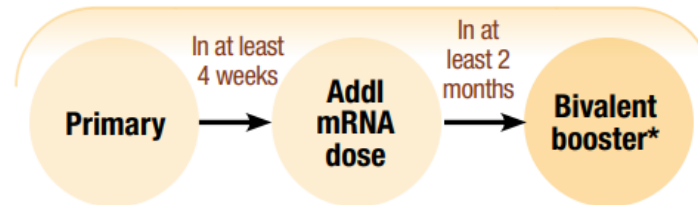


Novavax



-OR-

People ages 18 years and older who previously received Janssen primary series dose[†]



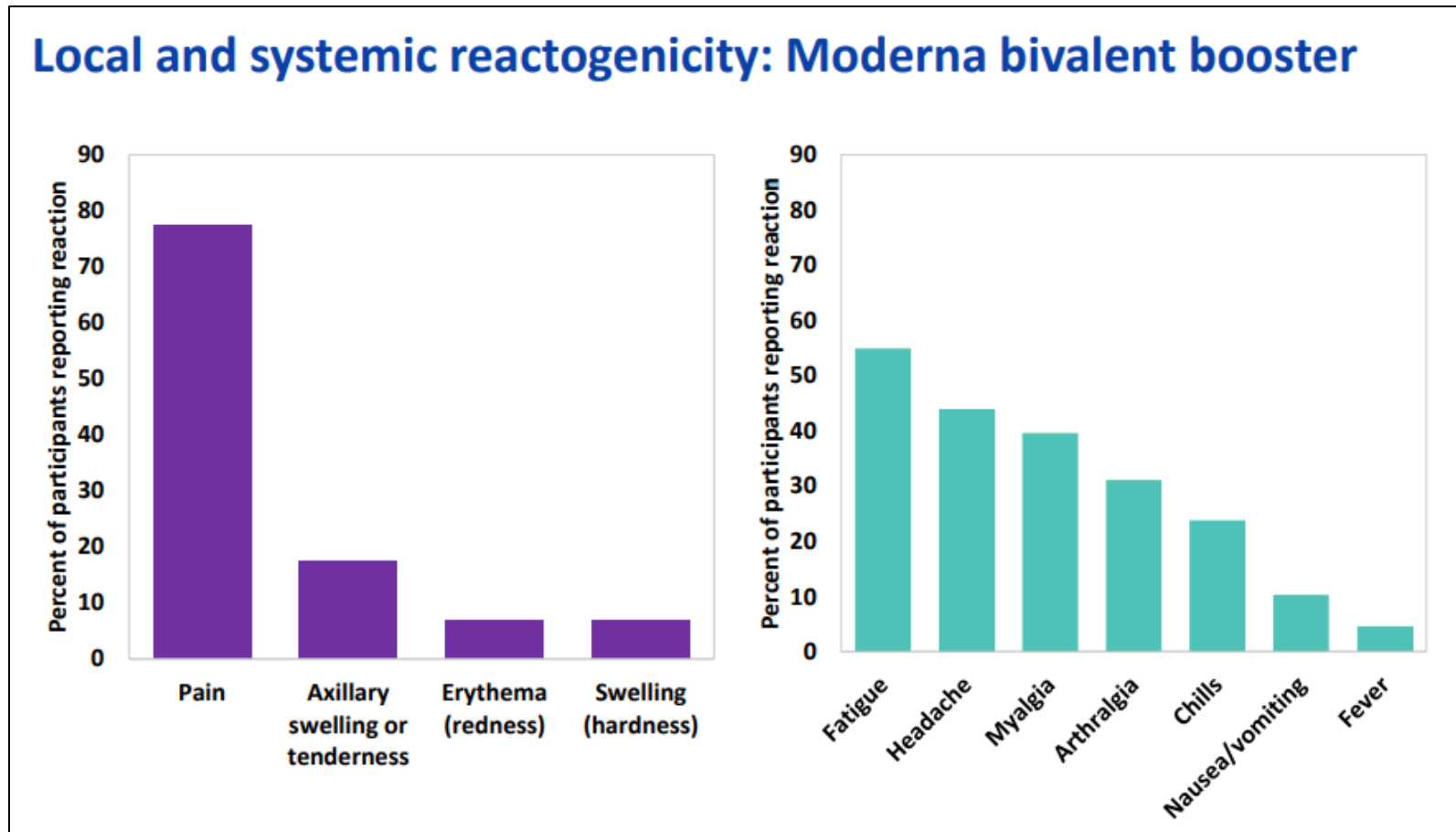
Importance of Receiving the Bivalent Booster

- Increased/better protection against currently circulating SARS-CoV-2 strains (BA.4/5) compared with monovalent vaccines
- Broader immune response and greater protection against past and likely future variants
- Potentially longer duration of protection
- Decrease in severe disease and healthcare utilization
- Timing vaccination before seasonal increase in COVID-19 can prevent infection and symptomatic disease, and help prevent lost days of productivity (school, work, etc.)

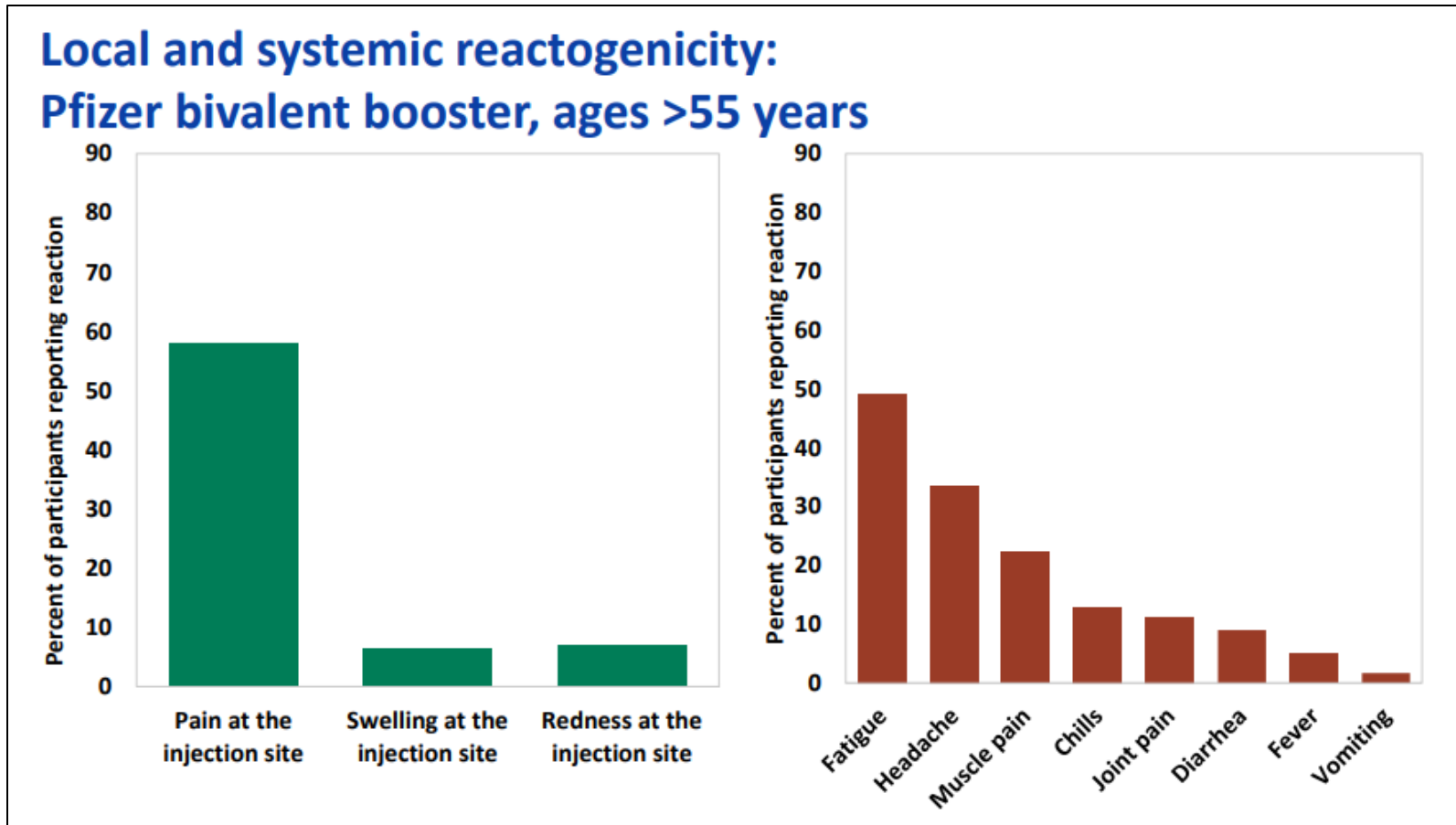
Why Are the Updated Boosters Recommended Without First Being Studied in Humans?

- Authorization and recommendation was based on past study of bivalent COVID-19 vaccines in people, including:
 - Moderna's bivalent Beta vaccine (mRNA-1273.211)
 - Moderna's bivalent Omicron BA.1 vaccine (mRNA 1273.214)
 - Pfizer-BioNTech's bivalent Omicron BA.1 vaccine
- Pfizer-BioNTech's and Moderna's bivalent Omicron BA.4/BA.5 vaccine is currently undergoing further immunogenicity and clinical study
- Updated vaccine boosters are expected to be safe and effective based on extensive use and study of the mRNA vaccine platform
 - Over 610 million doses of mRNA vaccine have been administered in the U.S.
 - Bivalent Omicron BA.4/BA.5 vaccines use the same vaccine technology and contain the same vaccine ingredients as existing mRNA vaccines

Local and Systemic Side Effects Are Common (Data From Moderna's BA.1 Omicron Bivalent Vaccine)

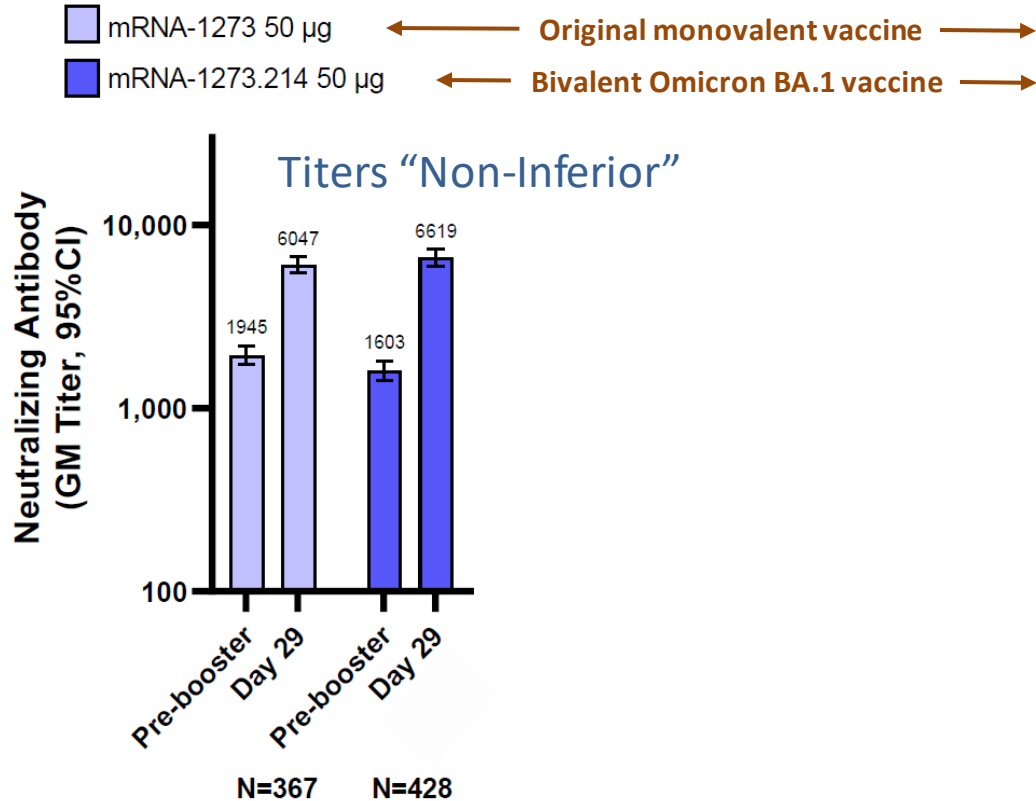


Local and Systemic Side Effects Are Common (Data From Pfizer's BA.1 Omicron Bivalent Vaccine)

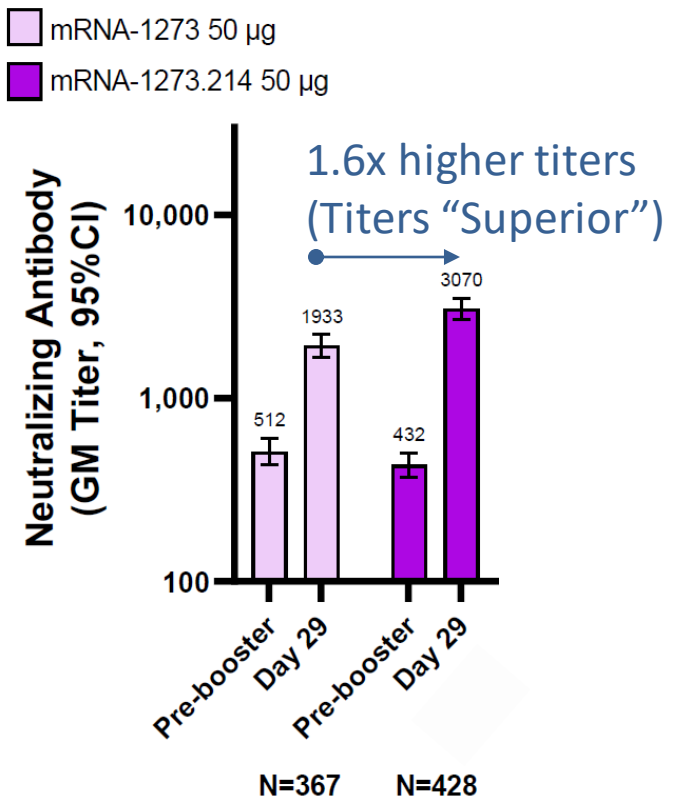


Neutralizing Antibody Response to Moderna's Bivalent Omicron BA.1 Booster (2nd booster)

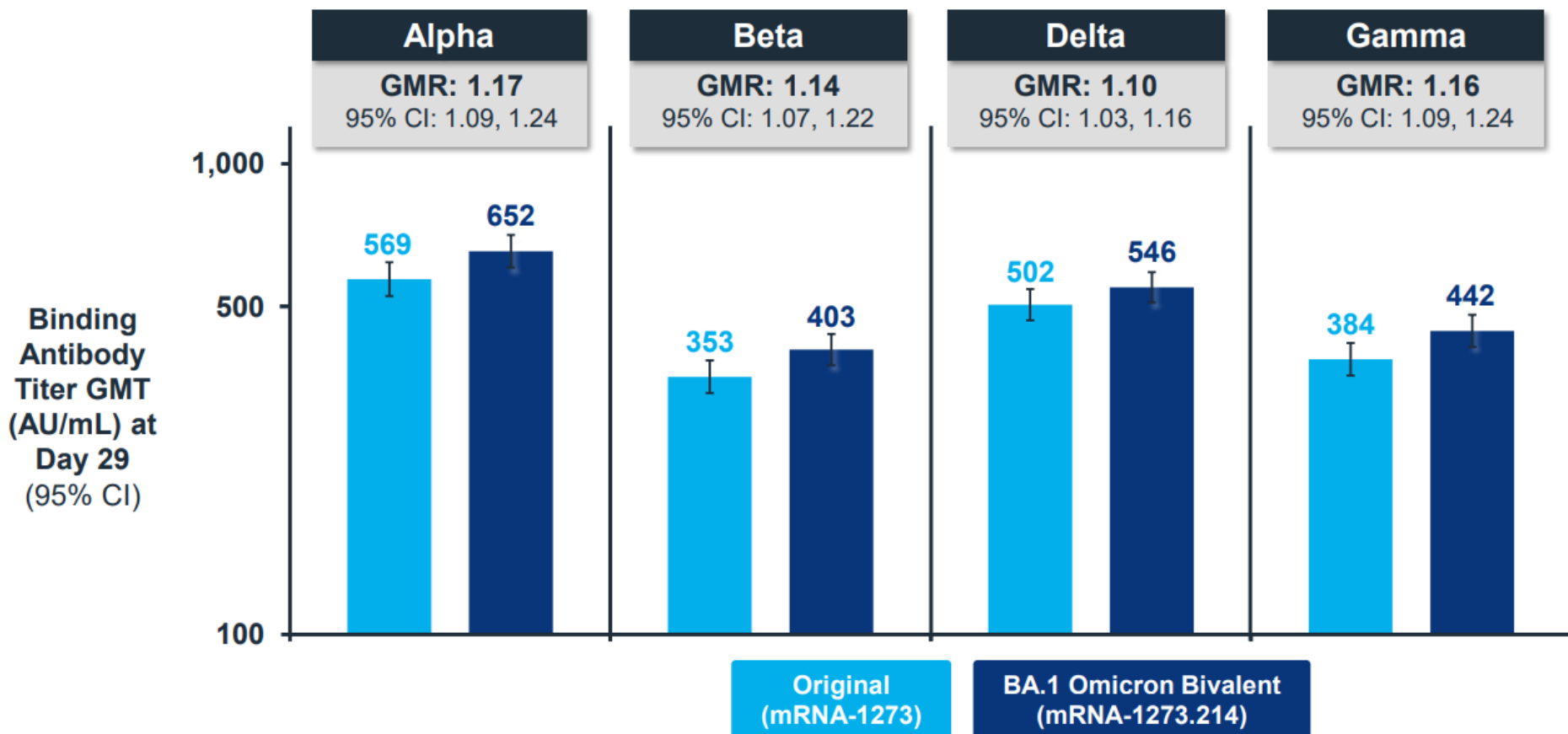
A. Ancestral SARS-CoV-2 (D614G)



B. Omicron

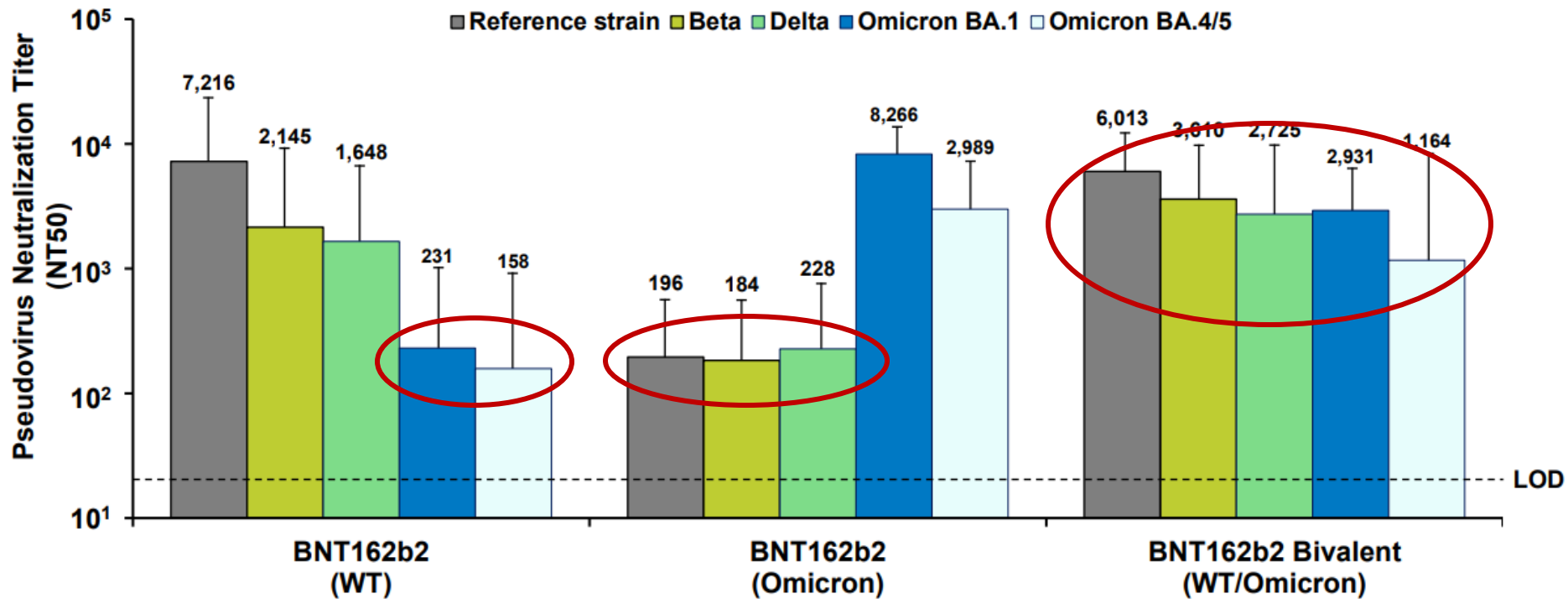


Bivalent Vaccines Provide Broad Protection Against Variants



Bivalent Vaccines Provide Broad Protection Against Variants

1M Post-Dose 2 in Naive Mice



When Will Children Under the Age of 12 Years Be Able to Get an Updated Omicron Booster?

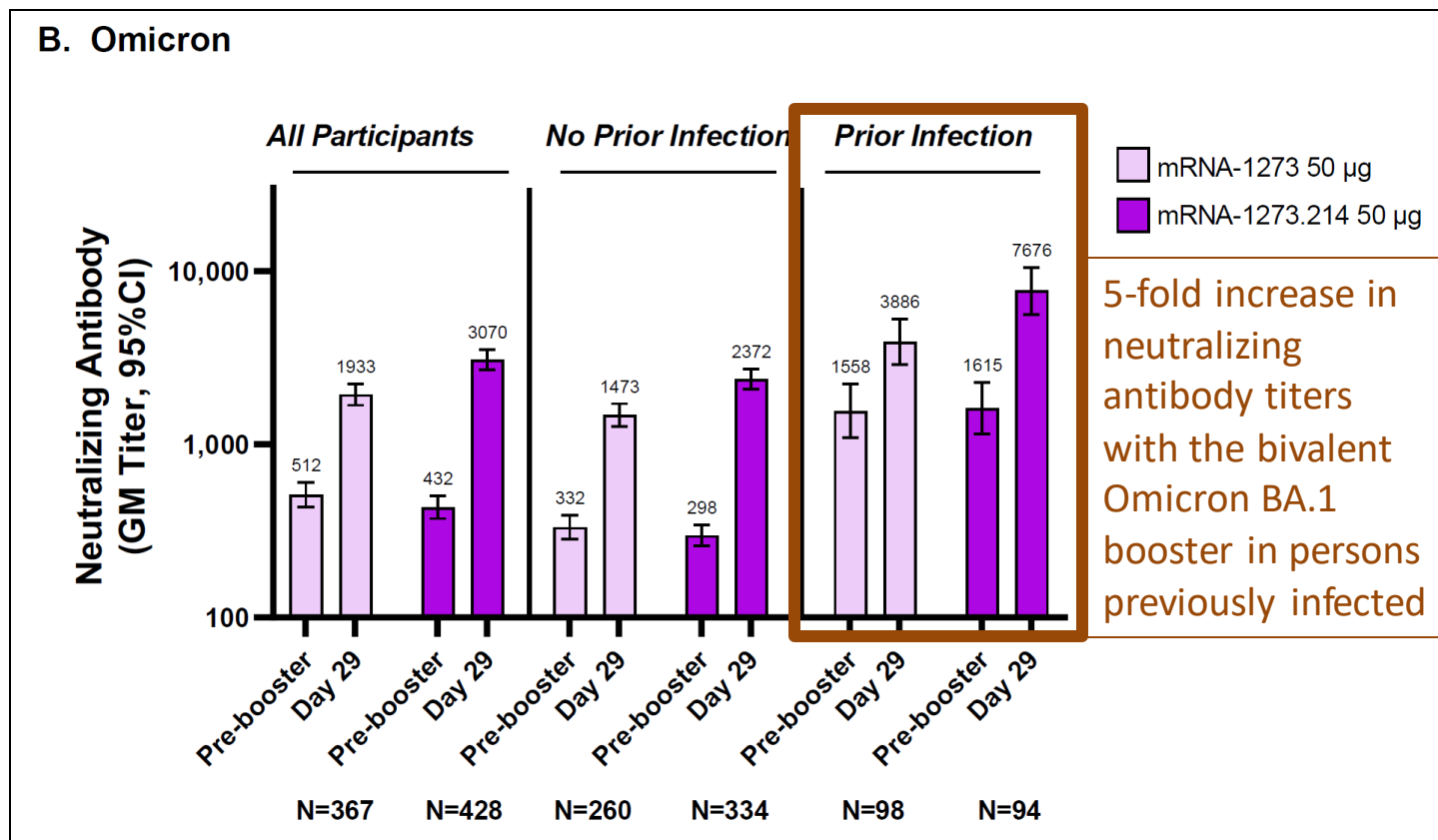
- We expect the updated bivalent boosters will be available and recommended for use in children (down to 5-6 years of age?) within the coming “weeks”

Will COVID-19 Vaccine Boosters be Needed Every Year?

- Studies have shown that vaccine protection decreases over time and with emergence of new SARS-CoV-2 variants
- Vaccine effectiveness against severe disease leading to hospitalization and death is greater and more durable, but protection still shows a slow decline over time (months)
- It is likely that COVID-19 vaccination will need “boosting” on a yearly basis with updated vaccines (similar to what occurs every influenza season)

Should Persons Previously Infected Also Get the Updated Omicron Booster?

- Yes – vaccination after prior infection (“hybrid” immunity) is important for higher and more durable protection



Can COVID-19 and Influenza Vaccines Be Given at the Same Time?

- Yes, COVID-19 vaccines can be given at the same time (i.e., same day and during same healthcare visit) with other routinely recommended vaccines, including influenza vaccine
- It remains important for people to also get the influenza vaccine this year – flu activity has been low the past two seasons, and we expect increased activity this year
 - Influenza vaccines this year contain 4 different influenza virus strains, including updated H3N2 and B/Victoria strains



COCA Call



CDC Clinician Outreach
and Communication Activity

2022-2023 Influenza Vaccination Recommendations and Guidance on Coadministration with COVID-19 Vaccines

Overview

During this COCA Call, presenters will provide updates on the Advisory Committee on Immunization Practices (ACIP) recommendations for the 2022-2023 influenza vaccination season, including information on a new preferential vaccine recommendation for adults ages 65 and older. In addition, presenters will outline guidance for the co-administration of the influenza and COVID-19 vaccines.

If you are unable to attend the live COCA Call, the recording will be available for viewing on the [COCA Call webpage](#) a few hours after the live event ends.



Date: Thursday, September 8, 2022

Time: 2:00 PM – 3:00 PM ET

Webinar Link:
<https://www.zoomgov.com>

Q&A