Immunization Updates 2022-2023

A presentation for Health Trust Members

March 22, 2023

Kat Dugan, PharmD, PGY-1 Resident

Cooperman Barnabas Medical Center

Preceptors:
Rachel Meyers, PharmD, BCPS, BCPPS, FPPA, Pediatric Clinical Pharmacist
Xinqi Liu, PharmD, Senior Transplant Pharmacist
Cooperman Barnabas Medical Center, Livingston, NJ

Speaker Disclosures

- The presenter and her preceptors have no relevant financial relationships with ineligible companies to disclose
- None of the planners for this education activity have relevant financial relationships to disclose with ineligible companies whose primary business is producing, marketing, selling re-selling, or distributing healthcare products used by or on patients
- This program may contain the mentions of suppliers, brand products, services or drugs presented in a case study or comparative format using evidence-based research. Such examples are intended for educational and information purposes only and should not be perceived an an endorsement of any particular supplier, brand, product, service, or drug

Learning Objectives: Pharmacists & Nurses

Identify	The indication and population of interest for mpox, pneumococcal, and COVID-19 vaccines
Recall	Administration considerations for the mpox, pneumococcal, and COVID-19 vaccines
Recognize	Adverse effects, contraindications, and vaccine schedule for mpox, pneumococcal, and COVID-19 vaccines in special patient populations

Learning Objectives: Pharmacy Technicians

Identify	The indication and population of interest for mpox, pneumococcal, and COVID-19 vaccines
Recall	Proper storage and preparation requirements for mpox, pneumococcal, and COVID-19 vaccines
Recognize	Inventory management and administrative procedures associated with mpox, pneumococcal, and COVID-19 vaccines

Mpox

JYNNEOS® and ACAM2000®

Overview

Organism

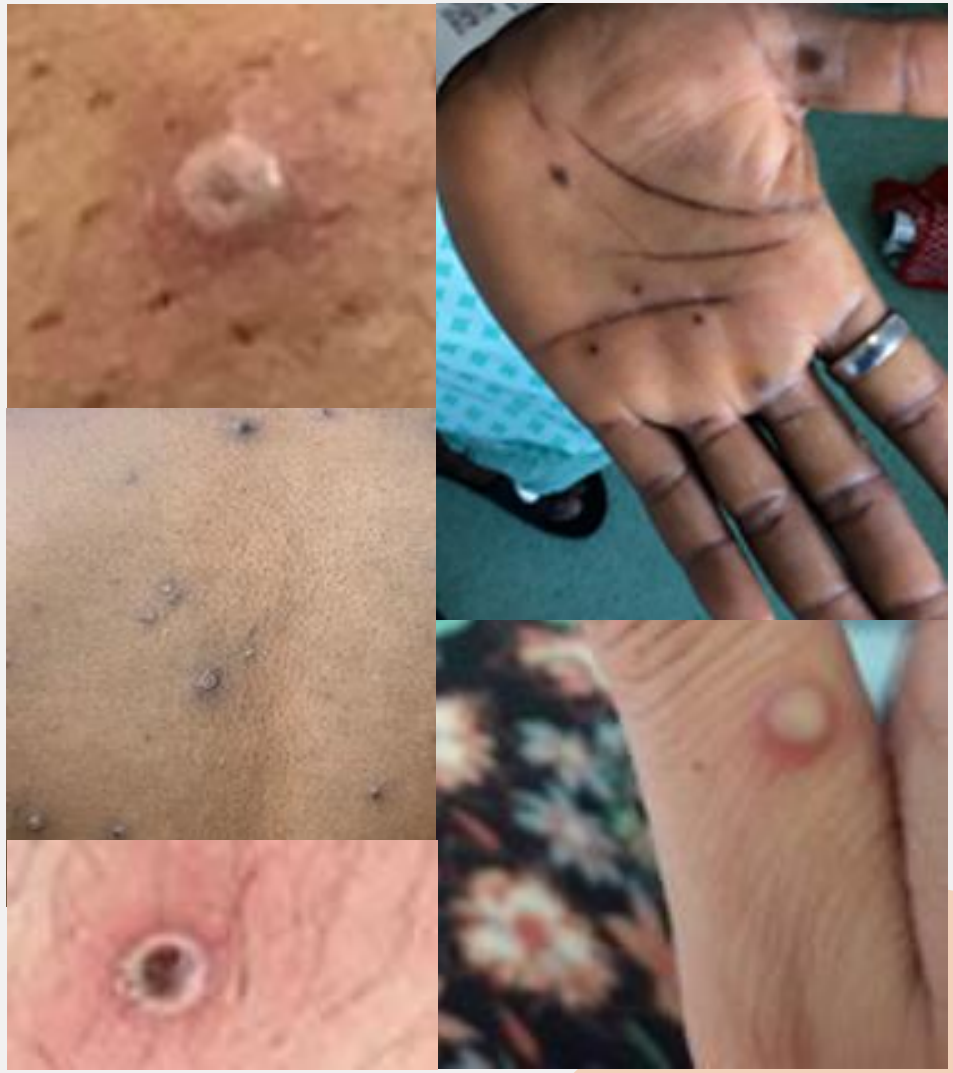
- Enveloped double-stranded DNA virus that belongs to the *Orthopoxvirus* genus of the *Poxviridae* family

Transmission

- Zoonotic
- Direct contact with blood, bodily fluids, or cutaneous/mucosal lesions of infected animals/humans
- Hosts: rope squirrels, tree squirrels, Gambian pouched rats, dormice, non-human primates and others

Clinical Presentation

- Symptom onset of 3-17 days
- Local symptoms: rash on hands, feet, chest, face, mouth, or near genitals
- Systemic symptoms: fever, chills, fatigue, myalgia, headache



Source: Centers for Disease Control and Prevention. Mpox. 2022.

Mpox Vaccine Timeline

2015-2018

- ACAM2000® the only orthopoxvirus vaccine licensed by the FDA

2019

- JYNNEOS® licensed in the United States

May 2022

- Mpox reported in countries where the disease is not endemic including the U.S.

June 2022

- U.S. national mpox vaccine strategy was announced
- FDA interim authorized ACAM2000® under Expanded Access Investigational New Drug (EA-IND) protocol for mpox

August 2022

- First mpox death in the U.S.
- FDA granted emergency use authorization (EUA) for JYNNEOS®

Source: Centers for Disease Control and Prevention. Mpox. 2022.

Mpox Vaccine Comparison of Biological and Pharmacological Characteristics

Characteristic	JYNNEOS® Vaccine	ACAM2000® Vaccine
Generic name	Smallpox and mpox vaccine, live, non-replicating	Smallpox vaccinia, vaccine, live, replicating
Produced from	Strain-modified Vaccinia Ankara-Bavarian Nordic (MVA-BN), an attenuated, non-replicating orthopoxvirus	Live vaccina virus derived by plaque purification from a previously calf lymph-produced vaccine (Dryvax®) and manufactured in Vero cells
Mechanism	Stimulates the immune system to develop antibodies and cells in the blood to fight against infection	
Dose(s)	2 dose series (28 days apart)	1 dose
Booster shots	Every 2-10 years*	Every 3 years†
Route of administration	Subcutaneous or intradermal	Percutaneous (scarification)

* For persons with ongoing occupational risk for exposure to orthopoxvirus infections. Designated public health and healthcare worker response teams approved by public health authorities should receive booster vaccination only at the time of an event, rather than at regular intervals.
† High risk of exposure, researchers working in laboratories handling "variola virus and mpox virus" should receive a booster dose every 3 years
Sources

Source:
Meo S et al. Vaccines (Basel). 2022; 10 (11):1971.
JYNNEOS. Package insert. Bavarian Nordic A/S ; 2022.
Centers for Disease Control and Prevention. JYNNEOS EUA HCP Fact Sheet. 2022.
ACAM2000. Package insert. Emergent BioSolutions Inc.; 2018.
Centers for Disease Control and Prevention. ACAM2000 Vaccine. 2022.

Mpox Vaccine Comparison of Immunogenicity, Contraindications, and Adverse Effects

Characteristics	JYNNEOS® Vaccine	ACAM2000® Vaccine
Immunogenicity	Two weeks after the second dose	Four weeks after the single dose
Risks in pregnancy, breastfeeding, infancy and children	May be administered	Contraindicated
Contraindication	Severe allergy to any component	Immunosuppression conditions*, history of atopic dermatitis or other exfoliative skin conditions, smoking, known underlying heart disease or ≥ 3 known major cardiac risk factors*, severe allergy to any component
Common adverse effects	Local: pain, redness, swelling, itching at the site of injection Systemic: fatigue, headache, myalgias, nausea, chills, fever	
Severe adverse effects	No risk of severe adverse effects	Increased risk of myopericarditis and cardiomyopathy

*HIV/AIDS, leukemia, lymphoma, generalized malignancy, solid organ transplantation, therapy with alkylating agents, antimetabolites, radiation, tumor necrosis factor inhibitors, or high-dose corticosteroids, being a recipient of a hematopoietic stem cell transplant <24 months ago or ≥24 months ago but with graft-versus-host disease or disease relapse, or having autoimmune disease with immunodeficiency as a clinical component

† Hypertension, diabetes, hypercholesterolemia, heart disease at age ≤50 years in a first-degree relative, and smoking

Source:
Meo S et al. Vaccines (Basel). 2022; 10 (11):1971.
JYNNEOS. Package insert. Bavarian Nordic A/S ; 2022.
Centers for Disease Control and Prevention. JYNNEOS EUA HCP Fact Sheet. 2022.
ACAM2000. Package insert. Emergent BioSolutions Inc.; 2018.
Centers for Disease Control and Prevention. ACAM2000 Vaccine. 2022.

Mpox Vaccine Comparison of Immunogenicity, Contraindications, and Adverse Effects

Characteristics	JYNNEOS® Vaccine	ACAM2000® Vaccine
Immunogenicity	Two weeks after the second dose	Four weeks after the single dose
Risks in pregnancy, breastfeeding, infancy and children	May be administered	Contraindicated
Contraindication	Severe allergy to any component	Immunosuppression conditions*, history of atopic dermatitis or other exfoliative skin conditions, smoking, known underlying heart disease or ≥ 3 known major cardiac risk factors*, severe allergy to any component
Common adverse effects	Local: pain, redness, swelling, itching at the site of injection Systemic: fatigue, headache, myalgias, nausea, chills, fever	
Severe adverse effects	No risk of severe adverse effects	Increased risk of myopericarditis and cardiomyopathy

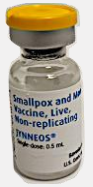
Preferred

*HIV/AIDS, leukemia, lymphoma, generalized malignancy, solid organ transplantation, therapy with alkylating agents, antimetabolites, radiation, tumor necrosis factor inhibitors, or high-dose corticosteroids, being a recipient of a hematopoietic stem cell transplant <24 months ago or ≥24 months ago but with graft-versus-host disease or disease relapse, or having autoimmune disease with immunodeficiency as a clinical component

† Hypertension, diabetes, hypercholesterolemia, heart disease at age ≤50 years in a first-degree relative, and smoking

Source:
Meo S et al. Vaccines (Basel). 2022; 10 (11):1971.
JYNNEOS. Package insert. Bavarian Nordic A/S ; 2022.
Centers for Disease Control and Prevention. JYNNEOS EUA HCP Fact Sheet. 2022.
ACAM2000. Package insert. Emergent BioSolutions Inc.; 2018.
Centers for Disease Control and Prevention. ACAM2000 Vaccine. 2022.

JYNNEOS® Additional Considerations



Medical condition or history	Interim guidance	Suggested action(s)
Severe gentamicin or ciprofloxacin allergy	Precaution	• Consider referral to an allergist-immunologist • 30-minute observation period following administration
Severe allergic reaction to chicken or egg protein **AND** currently avoiding exposure to all chicken or egg products	Precaution	• Consider referral to an allergist-immunologist • 30-minute observation period following administration
Moderate or severe acute illness, with or without fever	Precaution	• Consider deferring vaccination until the acute illness has improved

Source: Centers for Disease Control and Prevention. JYNNEOS. 2022

Mpox Vaccine Indications

Source:
Centers for Disease Control and Prevention. Components of the U.S. National Vaccination Strategy. 2023.
Centers for Disease Control and Prevention. Use of JYNNEOS for Preexposure Vaccination of Persons at Risk for Occupational Exposure to Orthopoxviruses. 2022.

Vaccination prior to exposure

- Certain laboratory workers*
- Those who administer ACAM2000® or care for patients infected with orthopoxviruses
- People who have been involved in high-risk sexual behaviors in the past 6 months†
- Patients with HIV or other causes of immunosuppression§

Post-exposure prophylaxis

- Known exposure within the past 14 days

* People at risk for occupational exposure to orthopoxviruses include research laboratory personnel working with orthopoxviruses, clinical laboratory personnel performing diagnostic testing for orthopoxviruses, and orthopoxvirus and health care worker response teams designated by appropriate public health and antiterror authorities.

† Gay, bisexual, and other men who have sex with men, and transgender or nonbinary people (including adolescents who fall into the aforementioned categories) who in the past 6 months have had:
- A new diagnosis of one or more sexually transmitted diseases (e.g., chlamydia, gonorrhea, syphilis); or
- More than one sex partner.

† People who have had any of the following in the past 6 months:
- Sex at a commercial sex venue; or
- Sex in association with a large public event in a geographic area where mpox transmission is occurring.
- Sexual partners of people with the above risks.

§ HIV/AIDS, leukemia, lymphoma, generalized malignancy, solid organ transplantation, therapy with alkylating agents, antimetabolites, radiation, tumor necrosis factor inhibitors, or high-dose corticosteroids, being a recipient of a hematopoietic stem cell transplant <24 months ago or ≥24 months ago but with graft-versus-host disease or disease relapse, or having autoimmune disease with immunodeficiency as a clinical component

JYNNEOS®

Storage

- Freezer (-25°C to -15°C)
- Refrigerator (2-8°C)

Beyond use dating (BUD)

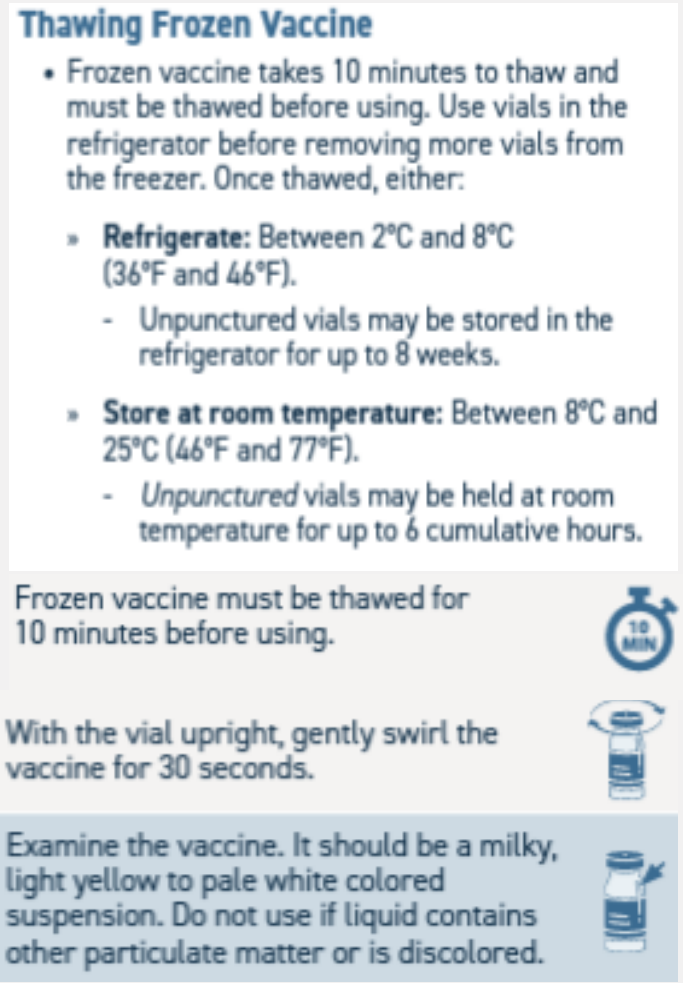
- Refrigerated, non-punctured vial: 8 weeks
- Refrigerated, punctured vial: 8 hours
- Room temperature (8-25°C), unpunctured vial: 6 hours

Preparation

- Thaw before use (10-15 minutes), do not refreeze

Administration

- 0.5 mL subcutaneous for individuals ≤18 years old
- 0.1 mL intradermal for individuals ≥18 years old
- Tuberculin syringe, 27 gauge, ¼" to ½" needle with a short bevel



Thawing Frozen Vaccine

- Frozen vaccine takes 10 minutes to thaw and must be thawed before using. Use vials in the refrigerator before removing more vials from the freezer. Once thawed, either:
  - **Refrigerate:** Between 2°C and 8°C (36°F and 46°F).
    - Unpunctured vials may be stored in the refrigerator for up to 8 weeks.
  - **Store at room temperature:** Between 8°C and 25°C (46°F and 77°F).
    - *Unpunctured* vials may be held at room temperature for up to 6 cumulative hours.

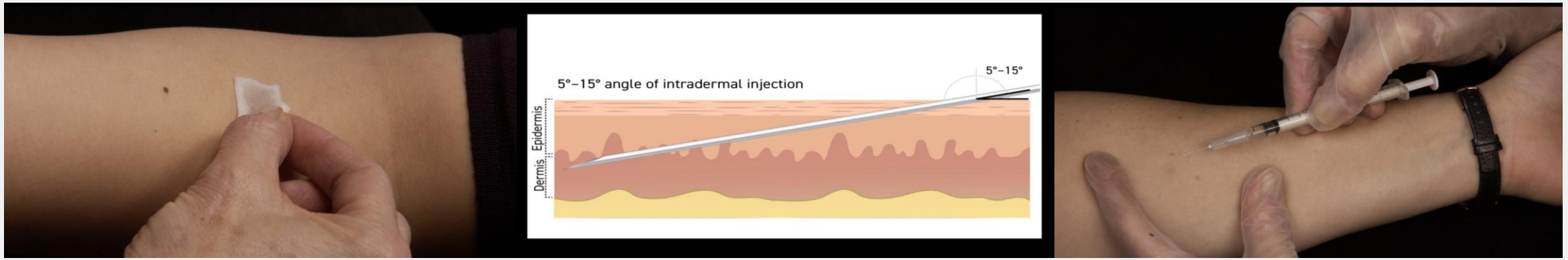
Frozen vaccine must be thawed for 10 minutes before using.

With the vial upright, gently swirl the vaccine for 30 seconds.

Examine the vaccine. It should be a milky, light yellow to pale white colored suspension. Do not use if liquid contains other particulate matter or is discolored.

Source: JYNNEOS. Package insert. Bavarian Nordic A/S ; 2022.

Intradermal Administration



Locate and clean a site for injection in the inner (volar surface of the forearm)

While pulling the skin taut, position the needle with the bevel facing up and insert the needle at a 5- to 15- degree angle into the dermis

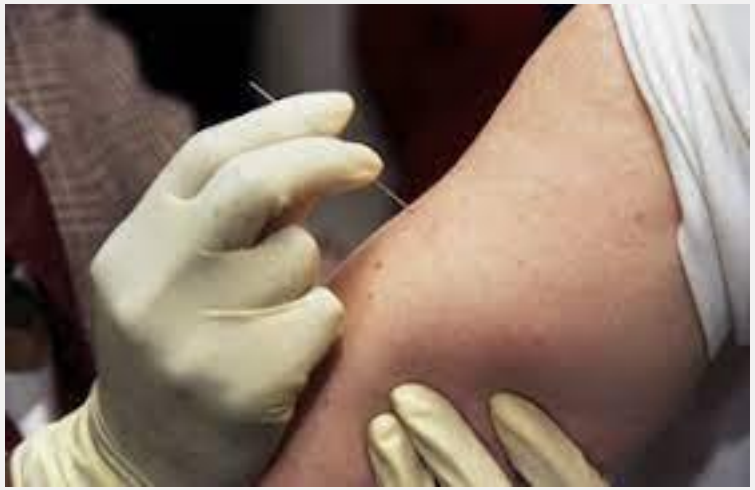
Slowly inject 0.1 mL intradermally

This should produce a noticeable pale elevation of the skin (wheal)

Observe patients for 15 minutes after vaccination or 30 minutes if they have a history of anaphylaxis to gentamicin, ciprofloxacin, chicken or egg protein

Source: Centers for Disease Control and Prevention. Smallpox and Monkeypox Vaccine Preparation and Administration Summary. 2022

ACAM2000®



Storage

- Freezer (15°C to -25°C)

BUD

- Room temperature (20-25°C), reconstituted: 6-8 hours
- Refrigerator (2-8°C), reconstituted: 30 days

Preparation

- Thaw before use, do not refreeze
- Reconstitute: 1 mL syringe fitted with a 25 gauge x 5/8" needle, 0.3 mL of diluent
- Gently swirl to mix
- The reconstituted vaccine should be a clear to slightly hazy, colorless to straw-colored liquid free from extraneous matter
- Inspect visually for particulate matter and discoloration prior to administration

Administration

- 1 single dose: 0.0025 mL droplet of reconstituted vaccine
- Percutaneous, delivered using a bifurcated needle

Source: ACAM2000. Package insert. Emergent BioSolutions Inc.; 2018.

Patient Case

DW is a 30-year-old female that presents to your clinic to inquire about vaccination for mpox.

Medical History	Allergies	Social History
• Hypertension	• Anaphylaxis to gentamicin (2020)	• Research laboratory personnel working with orthopoxviruses

Question 1 for Pharmacists and Nurses

Before administering the JYNNEOS® vaccine, what should you inform the patient about regarding their history of anaphylaxis to gentamicin?

A. The vaccine is contraindicated
B. The patient will need to be observed for 15 minutes after the vaccine is administered
C.The patient will need to be observed for 30 minutes after the vaccine is administered
D. The patient does not need to be observed after the vaccine is administered

Question 1 – Correct Response

Before administering the JYNNEOS vaccine, what should you inform the patient about regarding their history of anaphylaxis to gentamicin?

A. The vaccine is contraindicated
B. The patient will need to be observed for 15 minutes after the vaccine is administered
C. The patient will need to be observed for 30 minutes after the vaccine is administered
D. The patient does not need to be observed after the vaccine is administered

Question 1 for Pharmacy Technicians

If the patient refuses the vaccine and it has already been thawed, how long do you have before it expires?

A. 6 hours if punctured and refrigerated
B. 6 hours if unpunctured and refrigerated
C. 8 weeks if punctured and refrigerated
D. 8 weeks if unpunctured and refrigerated

Question 2 – Correct Response

If the patient refuses the vaccine and it has already been thawed, how long do you have before it expires?

A. 6 hours if punctured and refrigerated
B. 6 hours if unpunctured and refrigerated
C. 8 weeks if punctured and refrigerated
D. 8 weeks if unpunctured and refrigerated

Pneumococcal Pneumonia

PCV15 and PCV20

Overview

Organism

- *Streptococcus pneumoniae*
- Causes acute bacterial infections

Transmission

- Person-to-person through respiratory droplets or by autoinoculation
- More common during winter and early spring

Clinical Presentation

- Symptom onset of 1-3 days
- Pneumococcal pneumonia (most common)
  - Fever, chills, pleuritic chest pain, productive cough, rusty sputum, dyspnea, tachypnea, hypoxia, tachycardia, malaise, weakness
- Other presentations:
  - Bacteremia, sinusitis, meningitis, otitis media

Source: Centers for Disease Control and Prevention. Pneumococcal Disease. 2022.

Pneumococcal Vaccine Timeline

1977

- The first pneumococcal polysaccharide vaccine, containing 14 serotypes, was licensed for use

1983

- PPSV23 (Pneumovax23®) was licensed and replaced the 14-valent vaccine, which is no longer produced

2000

- PCV7 (Prevnar 7®), the first pneumococcal conjugate vaccine, was licensed for use

2010

- PCV13 (Prevnar 13®) was licensed for use

2021

- PCV15 (Vaxneuvance®) and PCV20 (Prevnar20®) were licensed for use

Source:
Gierke R, Wodi AP, Kobayashi M. Pink Book: Pneumococcal Disease. In: Pink Book. Washington, D.C: Public Health Foundation; 2021. p. 255–74.
Kobayashi M, Farrar JL, Gierke R, et al. Use of 15-Valent Pneumococcal Conjugate Vaccine and 20-Valent Pneumococcal Conjugate Vaccine Among U.S. Adults. 2022.

Pneumococcal Vaccine Types

Pneumococcal conjugate vaccine (PCV)

- Pneumococcal capsular polysaccharides covalently linked to a protein
- PCV13, **PCV15, PCV20**

Pneumococcal polysaccharide vaccine (PPSV)

- Partially purified pneumococcal capsular polysaccharides
- PPSV23

Source: Tereziu S, Minter DA. Pneumococcal Vaccine. 2022.

Adults ≥65 years old
Complete pneumococcal vaccine schedules

Prior vaccines	Option A	Option B
None*	**PCV20**	**PCV15** → ≥1 year† → **PPSV23**
PPSV23 only at any age	≥1 year → **PCV20**	≥1 year → **PCV15**
PCV13 only at any age	≥1 year → **PCV20**	≥1 year† → **PPSV23**
PCV13 at any age & **PPSV23** at <65 yrs	≥5 years → **PCV20**	≥5 years§ → **PPSV23**

* Also applies to people who received PCV7 at any age and no other pneumococcal vaccines
† Consider minimum interval (8 weeks) for adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak (CSF) leak
§ For adults with an immunocompromising condition, cochlear implant, or CSF leak, the minimum interval for PPSV23 is ≥8 weeks since last PCV13 dose and ≥5 years since last PPSV23 dose; for others, the minimum interval for PPSV23 is ≥1 year since last PCV13 dose and ≥5 years since last PPSV23 dose

Shared clinical decision-making for those who already completed the series with PCV13 and PPSV23

Prior vaccines	Shared clinical decision-making option
Complete series: PCV13 at any age & **PPSV23** at ≥65 yrs	≥5 years → **PCV20** Together, with the patient, vaccine providers **may choose** to administer PCV20 to adults ≥65 years old who have already received PCV13 (but not PCV15 or PCV20) at any age and PPSV23 at or after the age of 65 years old.

Source: Centers for Disease Control and Prevention. Pneumococcal Vaccine Timing for Adults. 2023

Adults 19–64 years old with specified immunocompromising conditions
Complete pneumococcal vaccine schedules

Prior vaccines	Option A	Option B
None*	**PCV20**	**PCV15** → ≥8 weeks → **PPSV23**
PPSV23 only	≥1 year → **PCV20**	≥1 year → **PCV15**
PCV13 only	≥1 year → **PCV20**	≥8 weeks → **PPSV23** → ≥5 years → **PPSV23** Review pneumococcal vaccine recommendations again when your patient turns 65 years old.
PCV13 and **1 dose of PPSV23**	≥5 years → **PCV20**	≥5 years† → **PPSV23** Review pneumococcal vaccine recommendations again when your patient turns 65 years old.
PCV13 and **2 doses of PPSV23**	≥5 years → **PCV20**	**No vaccines** recommended at this time. Review pneumococcal vaccine recommendations again when your patient turns 65 years old.
Immunocompromising conditions	▪ Chronic renal failure ▪ Congenital or acquired asplenia ▪ Congenital or acquired immunodeficiency§ ▪ Generalized malignancy ▪ HIV infection ▪ Hodgkin disease ▪ Iatrogenic immunosuppression¶ ▪ Leukemia ▪ Lymphoma ▪ Multiple myeloma ▪ Nephrotic syndrome ▪ Sickle cell disease/other hemoglobinopathies ▪ Solid organ transplant	

* Also applies to people who received PCV7 at any age and no other pneumococcal vaccines
† The minimum interval for PPSV23 is ≥8 weeks since last PCV13 dose and ≥5 years since last PPSV23 dose
§ Includes B- (humoral) or T-lymphocyte deficiency, complement deficiencies (particularly C1, C2, C3, and C4 deficiencies), and phagocytic disorders (excluding chronic granulomatous disease)
¶ Includes diseases requiring treatment with immunosuppressive drugs, including long-term systemic corticosteroids and radiation therapy

Source: Centers for Disease Control and Prevention. Pneumococcal Vaccine Timing for Adults. 2023

Adults 19–64 years old with a cochlear implant or cerebrospinal fluid leak
Complete pneumococcal vaccine schedules

Prior vaccines	Option A	Option B
None*	**PCV20**	**PCV15** → ≥8 weeks → **PPSV23**
PPSV23 only	≥1 year → **PCV20**	≥1 year → **PCV15**
PCV13 only	≥1 year → **PCV20**	≥8 weeks → **PPSV23** Review pneumococcal vaccine recommendations again when your patient turns 65 years old.
PCV13 and **1 dose of PPSV23**	≥5 years → **PCV20**	**No vaccines** recommended at this time. Review pneumococcal vaccine recommendations again when your patient turns 65 years old.

* Also applies to people who received PCV7 at any age and no other pneumococcal vaccines

Source: Centers for Disease Control and Prevention. Pneumococcal Vaccine Timing for Adults. 2023

Pneumococcal Vaccine Schedule: Pediatric Summary

For children ≤ 2 years of age

- PCV13 or PCV15
- Give as a series of 4 doses
- 2 months, 4 months, 6 months, 12 through 15 months

Children 2-4 years old without certain medical conditions who are unvaccinated or received an incomplete series

- 1 dose of PCV13 or PCV15

Source: Centers for Disease Control and Prevention. Pneumococcal Vaccination. 2023

Pneumococcal Vaccine Schedule:
2-5 Years Old with Certain Medical Conditions

Cerebrospinal fluid leak, chronic heart disease, particularly cyanotic congenital heart disease and cardiac failure, chronic lung disease, including asthma if treated with prolonged high-dose oral corticosteroid therapy, cochlear implant, diabetes mellitus

Prior Vaccines	Option A	Option B
None or incomplete PCV series before 24 months of age	2 doses PCV13†	2 doses PCV15†
3 doses of PCV series before 12 months	1 dose PCV13	1 dose PCV15
PCV series complete	1 doses of PPSV23	

†Give the second dose ≥8 weeks after the first

*Give the first dose ≥8 weeks after any prior pneumococcal conjugate vaccine dose

Source: Centers for Disease Control and Prevention. Pneumococcal Vaccination. 2023

Pneumococcal Vaccine Schedule:
2-5 Years Old with Certain Medical Conditions

Chronic renal failure or nephrotic syndrome, congenital immunodeficiency, B- (humoral) or T-lymphocyte deficiency, complement deficiency, particularly C1, C2, C3, or C4 deficiency, phagocytic disorder, excluding chronic granulomatous disease, congenital or acquired asplenia, or splenic dysfunction, diseases associated with treatment of immunosuppressive drugs or radiation therapy, HIV infection, sickle cell disease or other hemoglobinopathies

Prior Vaccines	Option A	Option B
None or incomplete PCV series before 24 months of age	2 doses PCV13†	2 doses PCV15†
3 doses of PCV series before 12 months	1 dose PCV13	1 dose PCV15
PCV series complete	2 doses of PPSV23*	

†Give the second dose ≥8 weeks after the first

*Give the first dose ≥8 weeks after any prior pneumococcal conjugate vaccine dose

*Give the second dose ≥5 years after the first PPSV23 dose

Source: Centers for Disease Control and Prevention. Pneumococcal Vaccination. 2023

Pneumococcal Vaccine Schedule: 6-18 Years Old with Certain Medical Conditions

Cerebrospinal fluid leak or cochlear implant

Prior Vaccines	Now	Later
None or incomplete PCV series before 24 months of age	1 dose of PCV13 or PCV15	1 dose of PPSV23 in ≥8 weeks

Immunocompromising conditions*

Prior Vaccines	Now	Later
None or incomplete PCV series before 24 months of age	1 dose of PCV13 or PCV15	2 doses of PPSV23 1st: in ≥8 weeks after any pneumococcal 2nd: ≥5 years after 1st dose

Chronic heart disease, chronic lung disease, diabetes mellitus

Prior Vaccines	Now
None or incomplete PCV series before 24 months of age	1 dose of PPSV23

Source: Centers for Disease Control and Prevention. Pneumococcal Vaccination. 2023

*See slide 31

Vaxneuvance® (PCV15)
Prevnar20® (PCV20)

Storage

- Refrigerator (2-8°C)
- Do not freeze
- Protect from light

BUD

- Prevnar20®: 96 hours when removed from refrigeration
- Prevnar15®: immediate use

Administration

- 0.5 mL single-dose syringe
- Intramuscular

Source:
Vaxneuvance. Package insert. Wyeth Pharmaceuticals LLC; 2022.
Prevnar20. Package insert. Merck & Co., Inc.; 2022.

Considerations for PCV15 and PCV20

Contraindication

- Anaphylaxis after a previous dose of a pneumococcal vaccine, or to any vaccine containing diphtheria toxoid

Precaution, but may administer

- Pregnant or breastfeeding
- Moderate or severe acute illness with or without fever

Adverse Reactions

Local:

Redness, soreness, swelling, itching

Systemic:

Fatigue (tiredness), headache, muscle pain

Source: Centers for Disease Control and Prevention. Pneumococcal Vaccination. 2023

Patient Case

CB is a 20-year-old with a cochlear implant and no other relevant past medical history who received the PCV7 vaccine during their routine childhood vaccination series. The patient presents to your clinic to inquire about the new pneumococcal vaccines because they googled that patients with cochlear implants should receive additional pneumococcal vaccines in their 20's.

Question 2 for Pharmacists and Nurses

Which, if any, pneumococcal vaccine should CB receive?

A.Not indicated for another pneumococcal vaccine at this time
B.1 dose of PPSV23 now, another dose 5 years later
C.1 dose of PPSV23 now, no further doses
D.1 dose of PCV20 now

Question 3 – Correct Response

Which, if any, pneumococcal vaccine should CB receive?

A.Not indicated for another pneumococcal vaccine at this time
B.1 dose of PPSV23 now, another dose 5 years later
C.1 dose of PPSV23 now, no further doses
D.1 dose of PCV20 now

Patient Case

MJ is a 65-year-old with no relevant past medical history or prior pneumococcal vaccinations who comes to your clinic to receive their routine vaccines who you have indicated to be eligible for either PCV20 or PCV15.

Question 3 for Pharmacists and Nurses

Which pneumococcal vaccine should CB receive?

A.1 dose of PCV20 now, no further doses
B.1 dose of PCV20 now, 1 dose of PCV20 in ≥1 year
C.1 dose of PCV15 now, no further doses
D.1 dose of PCV15 now, 1 dose of PCV15 in ≥1 year

Question 4 – Correct Response

Which pneumococcal vaccine should CB receive?

A. 1 dose of PCV20 now, no further doses
B. 1 dose of PCV20 now, 1 dose of PCV20 in ≥1 year
C. 1 dose of PCV15 now, no further doses
D. 1 dose of PCV15 now, 1 dose of PCV15 in ≥1 year

COVID-19

Bivalent Vaccines

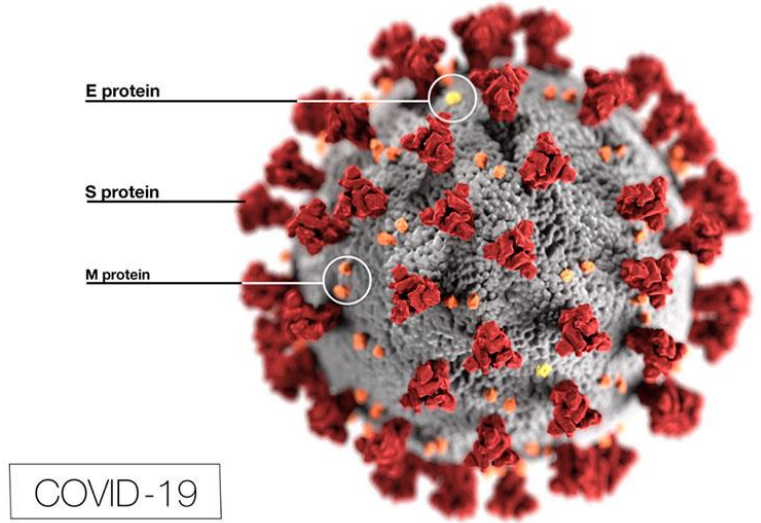
Overview

Organism

- COVID-19 is a respiratory disease caused by SARS-CoV-2
- A coronavirus discovered in 2019

Transmission

- Spreads from person to person through respiratory droplets and small particles produced when an infected person coughs, sneezes, or talks



Clinical Presentation

- Symptom onset of 2-14 days
- Fever, chills, fatigue, myalgia, headache
- New loss of taste or smell
- Congestion or runny nose, shortness of breath, cough, sore throat
- Nausea or vomiting, diarrhea

Source: Centers for Disease Control and Prevention. COVID-19. 2023.

mRNA History

1984

- Harvard University researches used a synthesized RNA enzyme to make biologically active messenger RNA (mRNA) in a lab

1987

- Human cells discovered to absorb mRNA and make proteins

1990

- Researchers tested mRNA as a treatment and vaccine in rats and mice, respectively, for influenza and cancer

2000s

- Several researchers studied mRNA treatments or vaccines

2005

- Discovery that modifying synthetic mRNA keeps the immune system from attacking the mRNA

2010s

- Many researchers studied mRNA treatments or vaccines

Source: Mayo Clinic. History of COVID-19: Outbreaks and vaccine timeline. 2023.

mRNA COVID-19 Vaccine Timeline

2019-2020

- WHO declared the COVID-19 outbreak a pandemic in 2020
- Many COVID-19 vaccine clinical trials were in process
- The FDA issued an EUA to two mRNA COVID-19 vaccines, the Pfizer-BioNTech and the Moderna COVID-19 vaccines

2021

- The FDA approves the Pfizer-BioNTech COVID-19 vaccine (Comirnaty®), to prevent COVID-19 in people ≥ 16 years old
- The FDA also authorized the Pfizer-BioNTech vaccine for children ages 5 through 15

2022

- FDA approval for:
  - Moderna COVID-19 vaccine (Spikevax®) ≥ 18 years old
  - Comirnaty® ≥ 12 years old
- FDA authorization for:
  - Spikevax® 6 months to 17 years old
  - Comirnaty® 6 months to 11 years old
  - Moderna Bivalent COVID-19 vaccine ≥18 years old
  - Pfizer-BioNTech Bivalent COVID-19 vaccine ≥ 12 years old

Source: Mayo Clinic. History of COVID-19: Outbreaks and vaccine timeline. 2023.

Adverse Reactions & Contraindications

Local

- Pain and swelling at the injection site

Systemic

- Fever, fatigue, headaches

Contraindications

- History of severe allergic reaction after a previous dose or to a component of the COVID-19 vaccines

Source: Centers for Disease Control and Prevention. Interim COVID-19 Immunization Schedule. 2022.

Considerations

Consideration	Guidance
Interchangeability	• Primary: Only in exceptional situations, not preferred • Booster: any mRNA vaccine can be used
Myocarditis and pericarditis risk	• Wait until after the episode has resolved before subsequent dose(s) are administered
Co-administration with other vaccines (ex. JYNNEOS®)	• COVID-19 vaccines may be administered on the same day as most other vaccines • Adolescent or young adult males may consider waiting 4 weeks after orthopoxvirus vaccination
History of multisystem inflammatory syndrome (MIS)	• Wait until clinical recovery and at least 90 days after diagnosis of MIS in children or adults
Moderate or severe acute illness	• Defer vaccination until person has recovered
Recent or current SARS-CoV-2 infection	• Consider delaying the next COVID-19 dose by 3 months from symptom onset or positive test (if infection was asymptomatic)
Pregnancy or breastfeeding	• Are recommended to be vaccinated
Persons receiving immunosuppressive therapies	• Whenever possible, administered ≥2 weeks before initiation or resumption of immunosuppressive therapies

Source: Centers for Disease Control and Prevention. Summary Document for Interim Clinical Considerations. 2022.

Storage, Preparation, Administration:

Moderna COVID-19 Bivalent Vaccine

Carton arrives frozen

Ultra-cold conditions in thermal containers with dry ice

Transfer to refrigerator

2-8˚C

Once thawed, do not refreeze

Carton of 10 single dose vials = 2 hours to thaw

Carton of 10 multiple dose vials = 6 hours to thaw

Store up to 30 days

Discard 12 hours after first puncture

Or Store at ultra-low temperature freezer

-50 to -15˚C

Store up to 12 months from the date of manufacture

Store at 9-25˚C

Up to 24 hours

Can be handled in room light conditions once thawed

Administration

Intramuscular

≥12 years old:

0.5 mL

6-11 years old:
0.25 mL

Source: Moderna COVID-19 Vaccine, Bivalent. Package insert. Moderna; 2022.

Storage, Preparation, Administration:

Pfizer-BioNTech COVID-19 Bivalent Vaccine

Carton arrives frozen

Ultra-cold conditions in thermal containers with dry ice

Transfer to refrigerator

2-8˚C

Once thawed, do not refreeze

Store up to 10 weeks

A carton of 10 single dose vials may take up to 2 hours to thaw at this temperature

A carton of 10 multiple dose vials may take up to 6 hours to thaw at this temperature

Or Store at ultra-low temperature freezer

-90 to -60˚C

Store up to 12 months from the date of manufacture

Do NOT store at -25 to -15˚C

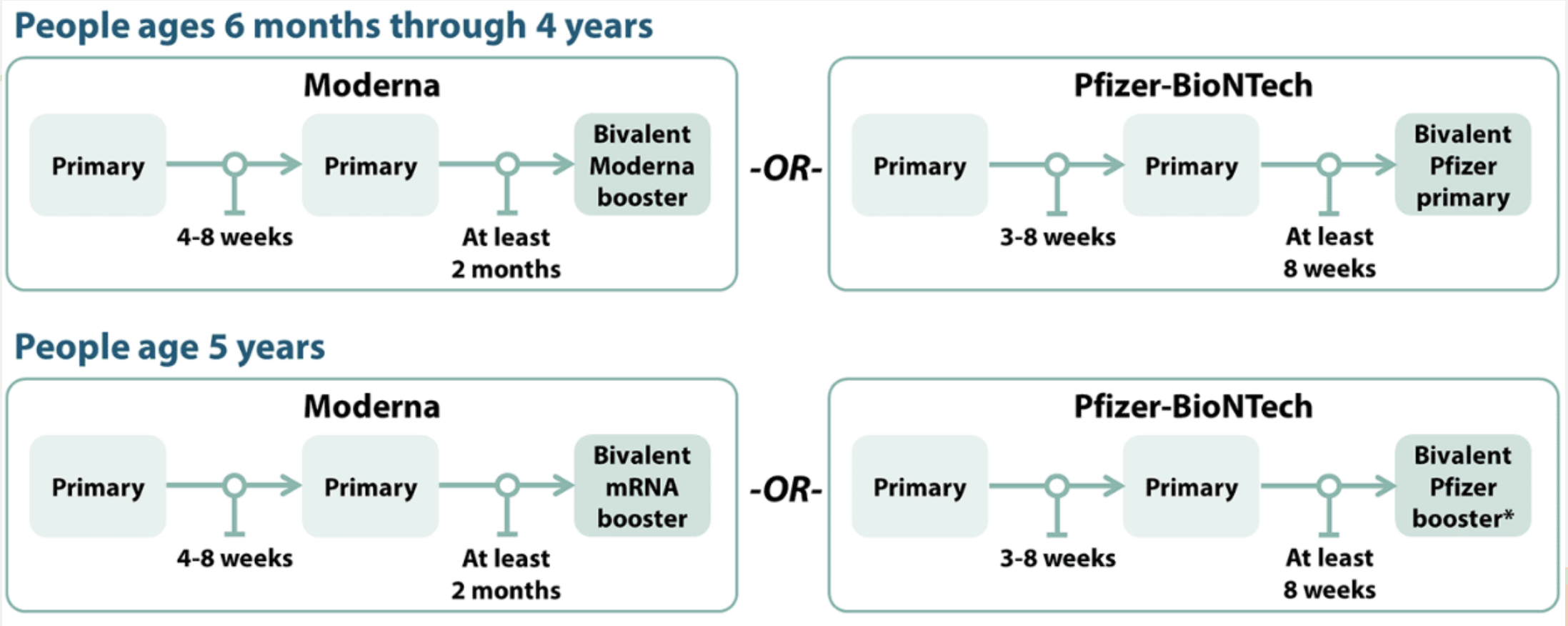
Administration

Intramuscular

0.2 mL

Source: Pfizer-BioNTech COVID-19 Vaccine, Bivalent. Package insert. Pfizer BioNTech; 2022.

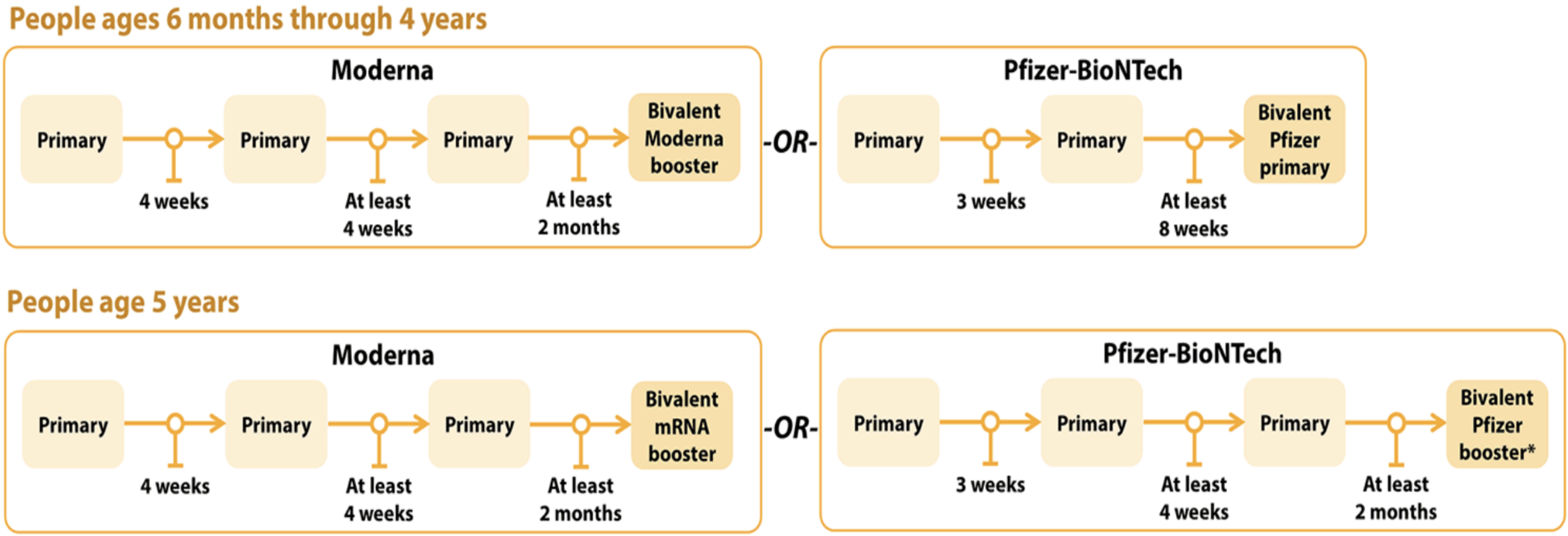
COVID-19 Immunization Schedule:
6 months-5 years old
Not moderately to severely immunocompromised



*For people who previously received a monovalent booster doses(s), the bivalent booster dose is administered at least 2 months after the last monovalent booster dose.

Source: Centers for Disease Control and Prevention. COVID-19 Vaccine Schedule Infographic. 2022.

COVID-19 Immunization Schedule:
6 months-5 years old
Moderately to severely immunocompromised



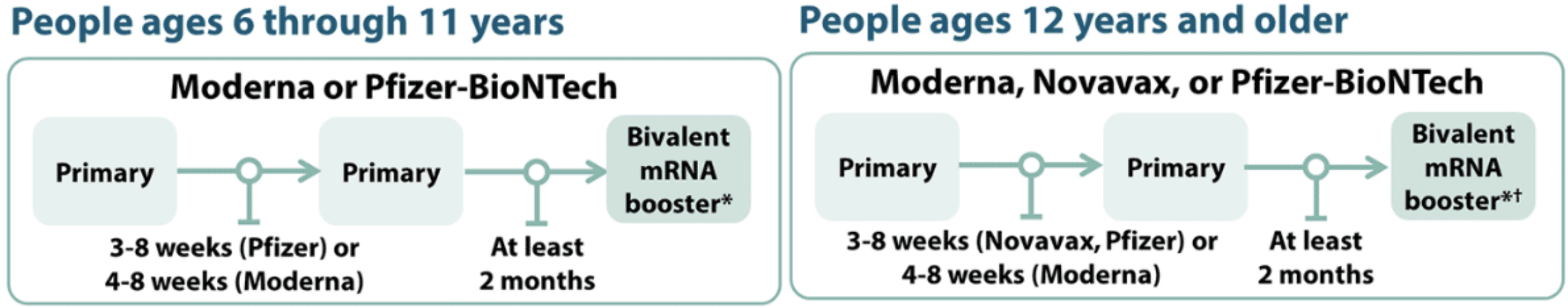
*For people who previously received a monovalent booster doses(s), the bivalent booster dose is administered at least 2 months after the last monovalent booster dose.

Source: Centers for Disease Control and Prevention. COVID-19 Vaccine Schedule Infographic (Immunocompromised). 2022.

COVID-19 Immunization Schedule:

≥6 years old

Not moderately to severely immunocompromised



*For people who previously received a monovalent booster doses(s), the bivalent booster dose is administered at least 2 months after the last monovalent booster dose.

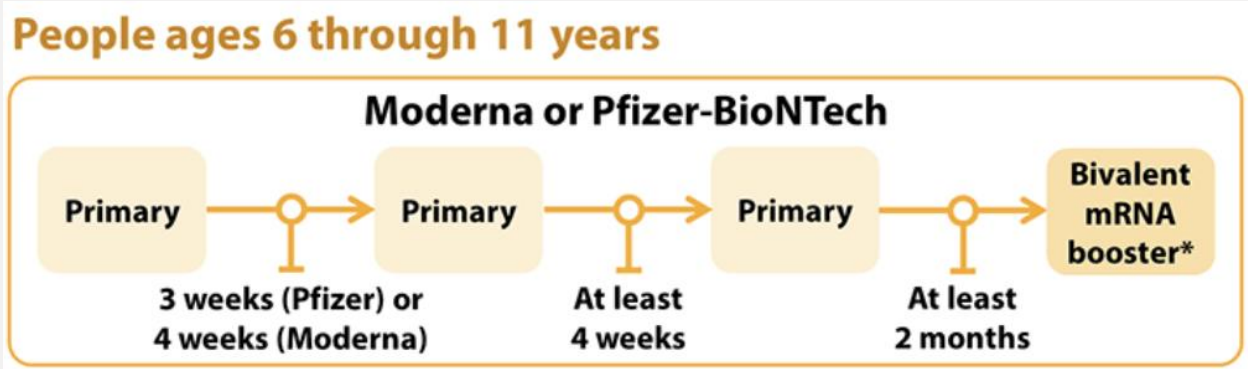
† A monovalent Novavax booster dose may be used in limited situations in people ≥18 years who completed a primary series using any COVID-19 vaccine, have not received any previous booster dose(s), and are unable or unwilling to receive an mRNA vaccine. The monovalent Novavax booster dose is administered at least 6 months after completion of a primary series.

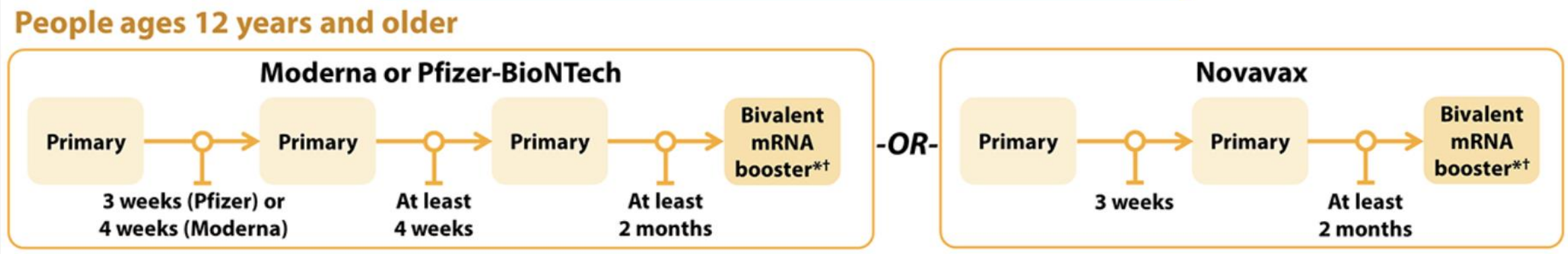
Source: Centers for Disease Control and Prevention. COVID-19 Vaccine Schedule Infographic. 2022.

COVID-19 Immunization Schedule:

≥6 years old

Moderately to severely immunocompromised





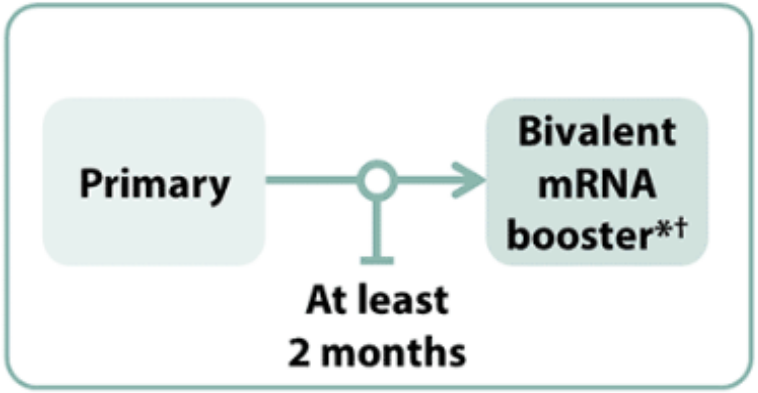
*For people who previously received a monovalent booster doses(s), the bivalent booster dose is administered at least 2 months after the last monovalent booster dose.

† A monovalent Novavax booster dose may be used in limited situations in people ≥18 years who completed a primary series using any COVID-19 vaccine, have not received any previous booster dose(s), and are unable or unwilling to receive an mRNA vaccine. The monovalent Novavax booster dose is administered at least 6 months after completion of a primary series.

Source: Centers for Disease Control and Prevention. COVID-19 Vaccine Schedule Infographic (Immunocompromised). 2022.

COVID-19 Immunization Schedule:
≥18 years old
Not moderately to severely immunocompromised

People ages 18 years and older who previously received Janssen primary series dose‡

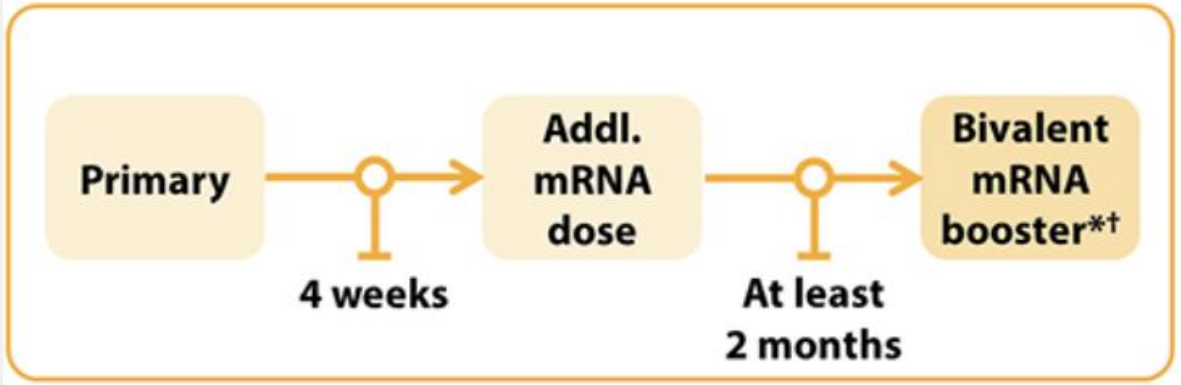


‡Janssen COVID-19 Vaccine should only be used in certain limited situations.
*For people who previously received a monovalent booster doses(s), the bivalent booster dose is administered at least 2 months after the last monovalent booster dose.
† A monovalent Novavax booster dose may be used in limited situations in people ≥18 years who completed a primary series using any COVID-19 vaccine, have not received any previous booster dose(s), and are unable or unwilling to receive an mRNA vaccine. The monovalent Novavax booster dose is administered at least 6 months after completion of a primary series.

Source: Centers for Disease Control and Prevention. COVID-19 Vaccine Schedule Infographic. 2022.

COVID-19 Immunization Schedule:
≥18 years old
Moderately to severely immunocompromised

People ages 18 years and older who previously received Janssen primary series dose‡



‡Janssen COVID-19 Vaccine should only be used in certain limited situations.
*For people who previously received a monovalent booster doses(s), the bivalent booster dose is administered at least 2 months after the last monovalent booster dose.
† A monovalent Novavax booster dose may be used in limited situations in people ≥18 years who completed a primary series using any COVID-19 vaccine, have not received any previous booster dose(s), and are unable or unwiling to receive an mRNA vaccine. The monovalent Novavax booster dose is administered at least 6 months after completion of a primary series.

Source: Centers for Disease Control and Prevention. COVID-19 Vaccine Schedule Infographic (Immunocompromised). 2022.

Patient Case

CM is a 25-year-old male who is seeking a booster vaccine for COVID-19. CM had his primary COVID-19 vaccination series on 8/11/21 & 9/4/21 with the Pfizer-BioNTech vaccine.

Question 2 for Pharmacy Technicians

Which COVID-19 vaccine should CM receive?

A. A 3rd dose of Comirnaty®
B. A dose of Moderna's Spikevax®
C. Pfizer-BioNTech bivalent vaccine
D. No booster is currently indicated

Question 2 – Correct Response

Which COVID-19 vaccine should CM receive?

A. A 3rd dose of Comirnaty®
B. A dose of Moderna's Spikevax®
C. Pfizer-BioNTech bivalent vaccine
D. No booster is currently indicated

Question 3 for Pharmacy Technicians

How should a vaccine administrator proceed if a carton of 10 single dose vials of Pfizer-BioNTech's new bivalent vaccine was retrieved from the freezer?

A. Discard appropriately
B. Thaw for 15-30 minutes and then prepare for administration
C. Thaw for 45-60 minutes and then prepare for administration
D.Thaw for 2 hours and then prepare for administration

Question 6 – Correct Response

How should a vaccine administrator proceed if a carton of 10 single dose vials of Pfizer-BioNTech's new bivalent vaccine was retrieved from the freezer?

A. Discard appropriately
B. Thaw for 15-30 minutes and then prepare for administration
C. Thaw for 45-60 minutes and then prepare for administration
D. Thaw for 2 hours and then prepare for administration

Other Vaccine Updates

Added Priorix® to the child and adolescent schedule

Added PreHevbrio™ and Priorix® to the adult schedule

Source: Centers for Disease Control and Prevention. Schedule Changes and Guidance. 2023.

Conclusion

- Continue to review and follow CDC recommendations for immunization practices
- Consider individual patient characteristics
- Counsel each patient on risks, benefits, and what to expect after each vaccine

References

1. Centers for Disease Control and Prevention. Mpox. 2022.
2. Meo S et al. Vaccines (Basel). 2022; 10 (11):1971.
3. JYNNEOS. Package insert. Bavarian Nordic A/S ; 2022.
4. ACAM2000. Package insert. Emergent BioSolutions Inc.; 2018.
5. Centers for Disease Control and Prevention. JYNNEOS. 2022
6. Centers for Disease Control and Prevention. Components of the U.S. National Vaccination Strategy. 2023.
7. Centers for Disease Control and Prevention. Use of JYNNEOS for Preexposure Vaccination of Persons at Risk for Occupational Exposure to Orthopoxviruses. 2022.
8. Centers for Disease Control and Prevention. Smallpox and Monkeypox Vaccine Preparation and Administration Summary. 2022
9. Centers for Disease Control and Prevention. Pneumococcal Disease. 2022.
10. Gierke R, Wodi AP, Kobayashi M. Pink Book: Pneumococcal Disease. In: Pink Book. Washington, D.C: Public Health Foundation; 2021. p. 255–74.
11. Kobayashi M, Farrar JL, Gierke R, et al. Use of 15-Valent Pneumococcal Conjugate Vaccine and 20-Valent Pneumococcal Conjugate Vaccine Among U.S. Adults. 2022.
12. Tereziu S, Minter DA. Pneumococcal Vaccine. 2022.
13. Centers for Disease Control and Prevention. Pneumococcal Vaccine Timing for Adults. 2023
14. Centers for Disease Control and Prevention. Pneumococcal Vaccination. 2023
15. Vaxneuvance. Package insert. Wyeth Pharmaceuticals LLC; 2022.
16. Prevnar20. Package insert. Merck & Co., Inc.; 2022.
17. Centers for Disease Control and Prevention. COVID-19. 2023.
18. Mayo Clinic. History of COVID-19: Outbreaks and vaccine timeline. 2023.
19. Centers for Disease Control and Prevention. Interim COVID-19 Immunization Schedule. 2022.
20. Moderna COVID-19 Vaccine, Bivalent. Package insert. Moderna; 2022.
21. Pfizer-BioNTech COVID-19 Vaccine, Bivalent. Package insert. Pfizer BioNTech; 2022.
22. Centers for Disease Control and Prevention. COVID-19 Vaccine Schedule Infographic. 2022.
23. Centers for Disease Control and Prevention. COVID-19 Vaccine Schedule Infographic (Immunocompromised). 2022.
24. Source: Centers for Disease Control and Prevention. Schedule Changes and Guidance. 2023.

Thank you!

Kat Dugan, PharmD, PGY-1 Resident

Cooperman Barnabas Medical Center

KATHERINE.DUGAN@rwjbh.org