

DISCLOSURE STATEMENT

We have had no financial relationship over the past 24 months with any commercial sponsor with a vested interest in this presentation.

PHARMACIST LEARNING OBJECTIVES

- 1. Summarize recent updates to the immunization schedule.
- Understand the guidance concerning contraindications and precautions related to influenza vaccinations.
- 3. Explain the "3 C's" of vaccine hesitancy.
- Identify tools that can be used to determine which vaccinations an individual may be eligible to receive.

TECHNICIAN LEARNING OBJECTIVES

- 1. Explain recent updates to the immunization schedule.
- 2. Understand the screening process for influenza vaccinations.
- 3. Recognize the importance of identifying vaccine hesitancy.
- 4. Identify which routine vaccinations are covered by Medicare Part D.



HEPATITIS B VACCINE

- Hepatitis B is a vaccine-preventable, communicable disease of the liver caused by hepatitis B virus (HBV)
- HBV vaccinations have been shown to be safe & effective for over 40 years
- Vaccination is recommended for all ages, however, vaccine coverage among adults is low
 - Rate of acute hepatitis infection rate in adults >40 years of age has been on the rise since 2012

Reference: HHS.gov Viral Hepatiti

HEPATITIS B VACCINE

- ACIP updated Hepatitis B vaccination recommendations April 1, 2022
 - Recommends all adults 19–59 years old receive a hepatitis B vaccination series
 - \circ $\,$ Those 60 and older without known risk factors may also receive the vaccine
 - Updated recommendations removes the need for risk factor screening
- Available vaccine(s)
 - Recombivax, Engerix, Heplisav (adjuvanted)
 - Other combo vaccines exist (Pediarix, Twinrix)

Reference: MMWR Morb Mortal Wkly Rep 2022;71:229-233.

PNEUMOCOCCAL VACCINE

• ACIP updated pneumococcal recommendations in January 2022

Reference: MMWR Morb Mortal Wkly Rep 2022;71:109-11

Reference: Pfiz

- Recommendations were "simplified" for healthcare providers
 - Includes both PCV20 and PCV15

PNEUMOCOCCAL VACCINE

CDC recommends pneumococcal vaccination for adults:

- 19 through 64 years old who have certain chronic medical conditions or other risk factors
- All adults 65 years or older

New recommendations:

- Series completion can occur with the use of:
 - PCV20 alone or PCV15 in series with PPSV23

PREVNAR 20™ (PNEUMOCOCCAL 20-VALENT CONJUGATE VACCINE)

- Provides protection against the following Streptococcus pneumoniae serotypes:
 - 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F
- Approved for adults <a>18 years

VAXNEUVANCE™ (PNEUMOCOCCAL 15-VALENT CONJUGATE VACCINE) Provides protection against the following Streptococcus pneumoniae

serotypes:

- I, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, and 33 F
- Approved for adults <u>></u>18 years

Reference: Merck Sharp & Dohme Corp.

Reference: CDC Pn













| Underlying medical | PPSV23** at 19 ti | brough 64 years | PPSV23** at 2 65 years | * Considered an | |
|---|--|---|--|--|--|
| condition or other risk | Recommended | Revaccination | Recommended | immunocompromising condition | |
| None | Not recommended | Not recommended | At least 1 year after PCV13 dose | Includes congestive heart failure and cardiomyopathies Includes chronic obstructive pulmonary disease, emphysema, | |
| Alcoholism | | | | and asthma | |
| Chronic heart disease! | | | ~ | 1 Includes B- (humoral) or | |
| Chronic liver disease | At least 1 year after | Not recommended | At least 1 year after | T-lymphocyte deficiency. | |
| Chronic lung disease ³ | PCV13 dose if PCV13 was inadvertently given | Not recommended | PCV13 dose and at least 5 years after any PPSV23 | complement deficiencies (particularly C1, C2, C3, and C4 | |
| Cigarette smoking | or given as a child | | 5 years after any PPSV23 close at < 65 years | | |
| Diabetes mellitus | | | | deficiencies), and phagocytic | |
| Cochlear implant | | | <u> </u> | disorders (excluding chronic granulomatous disease) | |
| Cerebrospinal fluid leak | At least 8 weeks after PCV13 dose | Not recommended | At least 8 weeks after PCV13 dose and at least 5 years after last PPSV23 dose at < 65 years | Includes diseases requiring treatment with immunosuppressive drugs, | |
| Chronic renal failure* | | | | including long-term systemic | |
| Congenital or acquired asplenia* | | | | corticosteroids and radiation therapy "For adults who have received PCV13 but have not completed | |
| Congenital or acquire immunodeficiency ^{*1} | | | | | |
| Generalized malignancy* | | | | their recommended pneumococcal | |
| HIV infection* | | | 1 | vaccine series with PPSV23, one dose of PCV20 may be used if PPSV23 is not available. If PCV20 is used, their pneumococcal | |
| Hodgkin disease* | ~ | ~ | At least 8 weeks after | | |
| latrogenic immunosuppression* ^s | At least 8 weeks after PCV13 dose | At least 5 years after first PPSV23 dose | PCV13 dose and at least 5 years after last PPSV23 | | |
| Leukemia* | | | dose at < 65 years | vaccinations are complete. | |
| Lymphoma* | | | | | |
| Multiple myeloma* | | | | | |
| Nephrotic syndrome* | | | | | |
| Sickle cell disease/other hemoglobinopathies* | | | | | |
| Solid organ transplant* | | | | | |

PNEUMOCOCCAL VACCINE RESOURCES

The PneumoRecs VaxAdvisor mobile app* helps vaccination providers quickly and easily determine which pneumococcal vaccines a patient needs and includes ACIP recommendations for all ages.

- Enter a patient's age
- Note if the patient has specific underlying medical conditions
- Answer questions about the patient's pneumococcal vaccination history



*Mobile app and Desktop version maybe downloaded at: nes/vpd/pneumo/hcp/pneumoapp.html

| The tool is very easy to use. Follow the prompts and answer questions pertaining to your patient to receive a recommendation. | | | | |
|---|--|--|--|--|
| Recommendation | Patient Characteristics | | | |
| Give one dose of PCV15 or PCV20. If PCV20 is used, their pneumococcal vaccinations are complete. If PCV15 is used, follow with one dose of PPSV23 to complete their pneumococcal vaccinations. The recommended interval between PCV15 and PPSV23 is at least 1 year. The minimum interval is 8 weeks and can be considered in adults with immunocompromising conditions ¹ , cochlear implants, or oerebrospinal fluid leaks. | Age: 19 through 64 years Risk Factors: Yes PCV13: No prior doses PPSV23: No prior doses | | | |

PATIENT CASE #1

Patient is a 75 year old male who received PCV13 three years ago. He is not immunocompromised. He presents to your pharmacy today to pick up his prescriptions and mentions his provider said he is due for another pneumonia shot.

· Which (if any) pneumococcal vaccine will you give him today?

PATIENT CASE #1

- Patient would be due for PPSV23 today
- What if PPSV23 isn't available? Per CDC guidance, can give one dose of PCV20 instead and series would still be considered complete





- An estimated 175 million doses of influenza vaccine distributed in the U.S. •
- No new safety concerns identified by the Vaccine Adverse Event Reporting • System (VAERS) Slight increase in flu activity in 2021-2022 season versus the year prior, but
- hospitalization rates remain lower than in the four season preceding the pandemic
- Rate was 5.2 hospitalizations per 100,000 individuals as of February 26, 2022
 The past two flu seasons have been described as "sporadic"
- Hard to produce efficacy estimates due to historically low flu activity in recent years
 Difficult to decide which strains to include in the vaccines
 Uncertainty about what the coming flu season will bring

eference: ACIP, Meds

SUMMARY OF 2021-2022 FLU SEASON

- CDC flu burden estimates from October 1, 2021 to June 11, 2022
 - Flu illness: 8 to 13 million
 - Flu hospitalizations: 82,000 to 170,000
 - Flu deaths: 5,000 to 14,000
- Vaccine efficacy studies as of January 2022 do not show statistically significant evidence that the flu vaccine was effective (only $\sim\!14\%$ effective against Flu A)
- Vaccination can decrease severe illness even if circulating viruses are different from the vaccine

Reference: CDC Flu Burden, Medscape, CDC Flu Dashboard

Reference: CDC ACIP Rec

SUMMARY OF 2021-2022 FLU SEASON

- Flu vaccine coverage for certain patient populations
 - Children: 55.3%
 - Adults 18-49 years: 34.7%
 - Adults 50-64 years: 50.0%
 - Adults 65 years and older: 67.7%
- Rates have decreased by 2-9.5% from previous year depending on the patient population
 Continued downward trend over past several years

Reference: CDC Flu Dasht

FLU VACCINES 2022-2023

- Influenza vaccination is recommended for everyone ≥ 6 months without contraindications
 - Emphasis on vaccinating high-risk groups and their caregivers/close contacts
- All approved vaccines are quadrivalent
 - 2 strains of influenza A and 2 strains of influenza B
 - Strains were updated this year
- The live, quadrivalent, intranasal flu vaccine; FluMist (LAIV4) is endorsed by American Academy of Pediatrics
 - \circ $\;$ Approved only for use in children and adults ages 2 through 49 years

FLU VACCINE STRAINS

| Egg-based IIV4s and LAIV4 | Cell-culture-based IIV4 and RIV4 |
|--|--|
| A/Victoria/2570/2019 (H1N1)pdm09-like | A/Wisconsin/588/2019 (H1N1)pdm09-like |
| A/Darwin/9/2021 (H3N2)-like | A/Darwin/6/2021 (H3N2)-like |
| B/Austria/1359417/2021 (Victoria lineage)-like | B/Austria/1359417/2021 (Victoria lineage)-like |
| B/Phuket/3073/2013 (Yamagata lineage)-like | B/Phuket/3073/2013 (Yamagata lineage)-like |

| Manufacturer | Trade Name (vaccine abbreviation) ¹ | How Supplied | Mercury Content (mcg Hg/0.5mL) | Immunize.org |
|------------------|---|---------------------------------------|--------------------------------------|----------------------------------|
| AstraZeneca | FluMist (LAIV4) | 0.2 mL (single-use nasal spray) | 0 | 2 through 49 years |
| GlaxoSmithKline | Fluarix (IIV4) | 0.5 mL (single-dose syringe) | 0 | 6 months & older ³ |
| Giaxosmitrikiine | FluLaval (IIV4) | 0.5 mL (single-dose syringe) | 0 | 6 months & older ³ |
| | Flublok (RIV4) | 0.5 mL (single-dose syringe) | 0 | 18 years & older |
| | | 0.5 mL (single-dose syringe) | 0 | 6 months & older ³ |
| | E (1974) | 0.5 mL (single-dose vial) | 0 | 6 months & older ³ |
| Sanofi | Fluzone (IIV4) | 5.0 mL multi-dose vial (0.25 mL dose) | 25 | 6 through 35 months ³ |
| | | 5.0 mL multi-dose vial (0.5 mL dose) | 25 | 6 months & older |
| | Fluzone High-Dose (IIV4-HD) | 0.7 mL (single-dose syringe) | 0 | 65 years & older |
| | | 5.0 mL multi-dose vial (0.25 mL dose) | 24.5 | 6 through 35 months ³ |
| | Afluria (IIV4) | 5.0 mL multi-dose vial (0.5 mL dose) | 24.5 | 3 years & older |
| Segirus | | 0.5 mL (single-dose syringe) | 0 | 3 years & older ³ |
| Jequus | Fluad (allV4) | 0.5 mL (single-dose syringe) | 0 | 65 years & older |
| | Flucelvax (ccIIV4) | 0.5 mL (single-dose syringe) | 0 | 6 months & older ³ |
| | Fluceivax (ccliv4) | 5.0 mL multi-dose vial (0.5 mL dose) | 25 | 6 months & older3 |

FLU VACCINES 2022-23

- Change in age indication for Flucelvax Quadrivalent
 - Cell-culture based quadrivalent inactivated influenza vaccine (ccllV4)
 - Approved in October 2021 for ages ≥6 months
- Now there is an egg-free vaccine available for those as young as 6 months of age

Reference: AC

FLU VACCINES 2022-23

- Adults aged 65 years and older
 - New recommendation from June 2022 ACIP meeting
 - Should receive one of the following enhanced influenza vaccinations (EIV):
 Quadrivalent high-dose inactivated influenza vaccine (HD-IIV4)
 - Fluzone High-Dose Quadrivalent
 - Quadrivalent adjuvanted inactivated influenza vaccine (allV4)
 - Fluad Quadrivalent
 Quadrivalent recombinant influenza vaccine (RIV4)
 - Flublok Quadrivalent
 - No preference for any one of these three vaccines over the other two
 - If none of these are available at an opportunity for vaccine administration, then **any other**
 - age-appropriate influenza vaccine should be used

FLU VACCINES 2022-23

Immunocompromised patients

May receive any age-appropriate injectable flu vaccine

Severe egg allergy

- People with a history of egg allergy of any severity should receive any licensed, recommended, and age-appropriate influenza vaccine
- Severe egg allergy is classified as symptoms more severe than hives
 Can usually tolerate any flu vaccine but should receive in a medical setting with supervision
- Flublok Quadrivalent and Flucelvax Quadrivalent are eaa-free

Reference: CDC ACIP Recommendations

VACCINATION TIMING

- Timing of flu outbreaks is unpredictable
- Ideally administered by the end of October
- Continue to offer as long as virus is circulating locally and vaccine is available
 Influenza vaccination during July and August should be avoided in non-pregnant adults
- unless there is concern that later vaccination might not be possible
 - Vaccination too early in the season may lead to suboptimal immunity later on, particularly among older adults
 - Not recommended to repeat a flu vaccine due to fears of waning from vaccinating early in the season

Reference: ACIP

ce: AC

VACCINE TIMING FOR CHILDREN

- Children 6 months to 8 years should receive two doses if they have not received at least two doses previously
- Should receive the first dose as soon as possible
 - Second dose should be given at least 4 weeks later
 - Does <u>NOT</u> have to be the same vaccine product for both doses
 Pay attention to dose volume if vaccinating children 6 to 35 months
- For children who need two doses, if the child turns nine years old between doses one and two of the vaccine, two doses are still recommended
 - Vaccination may occur as soon as vaccine is available
 - Less evidence to suggest that early vaccination is associated with waning immunity among children as compared with adults

Reference: ACIP, Michigan.go

COADMINISTRATION OF COVID-19 AND INFLUENZA VACCINATIONS

- Current guidance indicates that the COVID-19 vaccines may be given with other vaccines
 Encouraged by the CDC to avoid missed opportunities to vaccinate
- No data currently available concerning coadministration of authorized COVID-19 vaccines and influenza vaccines
 - Potential for increased reactogenicity
- If coadministered, COVID-19 vaccines and those that might be more likely to cause a local reaction (Fluad Quadrivalent or Fluzone High-Dose Quadrivalent) should be administered in different limbs, if possible



| | S | State Profile Rep | Dakota | Reference: US DHHS. COVID-19 State Profile Report-South |
|-------------|--------------------|-------------------------------|--------------------|---|
| | | State Vaccinat | ion Summary | |
| Dos | es Delivered | 2,128,765 240,631 per 100k | Doses Administered | 1,507,783 170,437 per 100k |
| Age Group | At Least One D | ose Full | y Vaccinated | Booster Dose† |
| Total | 699,563 (79.1%) | | 562,437 (63.6%) | 248,112 (44.1%) |
| <5 years | 2,348 (3.8%) | | 164 (0.3%) | N/A |
| 5-11 years | 29,289 (34.3%) | | 23,088 (27.0%) | 2,605 (11.3%) |
| 12-17 years | 46,410 (65.8%) | | 36,099 (51.2%) | 9,093 (25.2%) |
| 18+ years | 621,416 (93.1%) | | 503,072 (75.4%) | 236,411 (47.0%) |
| 65+ years | 182,044 (95.0%) | | 150,956 (95.0%) | 98,689 (65.4%) |

| | | | re: Vaccinat | |
|-------------|------------------------|---------------------------------|---------------------------------|---------------------------------|
| Dos | es Delivered | 806,829,135 243,014 per 100k | Doses Administered | 608,937,334 183,410 per 100k |
| Age Group | At Least One | Dose F | ully Vaccinated | Booster Dose† |
| Total | 262,643,27 (79.1%) | 7 | 223,914,723 (67.4%) | 108,540,822 (48.5%) |
| <5 years | 1,018,498 (5.2%) | | 221,851 (1.1%) | N/A |
| 5-11 years | 10,913,583 (38.0%) | | 8,774,347 (30.5%) | 1,214,615 (13.8%) |
| 12-17 years | 17,865,954 (70.6%) | | 15,281,885 (60.4%) | 4,409,197 (28.9%) |
| 18+ years | 232,674,052 (90.1%) | 2 | 199,551,723 (77.3%) | 102,915,219 (51.6%) |
| 65+ years | 57,449,108 (95.0%) | | 50,415,834 (92.0%) | 35,599,077 (70.6%) |
| ' | | | Reference: US Department of Hea | Ith and Human Services. COVI |







- doses for all vaccine-eligible people 18 years of age and older Janssen COVID-19 vaccine should only be used in limited situations due to risk of thrombosis with
- thrombocytopenia syndrome (TTS) Vaccine should be given at least 2 weeks before initiation or resumption of immunosuppressive therapies
- Studies in adolescents and adults have shown the small risk of myocarditis associated with mRNA
 - vaccines might be reduced and vaccine effectiveness increased with an interval longer than 4 weeks • 8-week interval may be optimal for those who are not immunocompromised and ages 6 months-

Reference: CDC Interim COVID-19 Immu

64 years, especially for males ages 12–39 years old



CHILDREN TRANSITIONING FROM A YOUNGER TO OLDER AGE GROUP

- CDC recommends children receive the age-appropriate vaccine product and dosage based
- on their age on the day of vaccination
 - If a child moves from a younger group to an older group during the primary series or between the primary series and booster, give the vaccine product and dosage for the older age group for all subsequent doses
 - If inadvertently continued with lower dose, it is <u>NOT</u> considered an error and the primary series is still considered complete
- Many caveats and gets confusing quickly
 - Use CDC recommendations to ensure the correct vaccine product and dose is used

Reference: CDC Moderna/Pfizer COVID-19 Vaccine for Children who Transition from a Younger to Older Age









| IM | IODERNA VACO | CINE PRODUCT | 'S |
|----------------------------|---------------------------------------|----------------------------------|---|
| Authorized Age group | 6 months –5 years (primary series) | • 6–11 years (primary series) | • 12 years and olde (primary series) |
| Vial cap color | Dark blue | Dark blue | Red |
| Label border color | Magenta | Purple | Light blue |
| Dose (mRNA concentration) | 25 mcg | 50 mcg | 100 mcg |
| Injection volume volume | 0.25 mL | 0.5 mL | 0.5 mL(primary, age 12+) |
| Dilution required | No | No | No |
| Doses per vial | 10 | 5 | Maximum of 11 |

BIVALENT BOOSTER VACCINES

- The FDA approved bivalent COVID-19 booster vaccines on August 31, 2022
- The ACIP followed with approval on September 1, 2022
- New boosters are bivalent, meaning "original" vaccine + an Omicron variant component Designed to generate immune responses to the original version of the coronavirus vaccine and to
- BA.5 (the Omicron subvariant that is now dominant) Inclusion of a second SARs-COV-2 variant into the vaccine broadens the antibody response
- As with monovalent, the bivalent boosters are interchangeable
- May receive a Pfizer or Moderna booster that is different from the primary series or last booster dose
- Cannot get a bivalent booster without first completing at least a primary seri
- If recently had COVID, should wait at least until symptoms have resolved before getting a booster
 - May want to wait a full three months after COVID-19 infection



PFIZER-BIONTECH BIVALENT VACCINE

Authorization: for use in individuals 12 years of age and older as a single booster dose administered at least 2 months after either:

ast 2 months after either: Completion of primary vaccination with any monovalent COVID-19 vaccine, or · Receipt of the most recent booster dose with any monovalent COVID-19 vaccine

Dose: 0.3 mL

Storage:

Thawed vials may be kept at refrigerated temps (35°F to 46°F) for up to 10 weeks prior to use

- May be stored at room temperature (46°F to 77°F) for a total of 12 hours prior to the first puncture After first puncture, vial should be held between 35°F to 77°F then discarded 12 hours after first puncture
- Vials:

• Vials are multi-dose and contain 6 doses per vial (do NOT dilute)

Pfizer bivalent vials have **GRAY** colored caps (same as the current monovalent product) but labels differentiate the formulations

MODERNA BIVALENT VACCINE

Authorization: for use in individuals 18 years of age and older as a single booster dose administered at least 2 months after either:

 Completion of primary vaccination with any monovalent COVID-19 vaccine, or
 Receipt of the most recent booster dose with any monovalent COVID-19 vaccine Dose: 0.5 mL

Storage:

Store at refrigerated temperatures of 36°F to 46°F after thawing from frozen storage

- Vials may be stored refrigerated between 36°F to 46°F for up to 30 days prior to first use
- $\,$ Punctured vials should be held at 46 $^\circ F$ to 77 $^\circ F$ and discarded 12 hours after the first puncture Vials:

Vials are multi-dose and contain 5 doses per vial (no dilution) · Same size as previous Moderna vials and have a dark blue vial cap

Reference: Moderna Bivalent EL

ence: Novavax, Inc.; Pharmacy Ti

CDC COVID-19 VACCINE BOOSTER TOOL Quickly determine if a patient is eligible for a booster Includes vaccine product option(s) and dosing intervals Scroll down and click "Find Out When to Get a Booster" link Enter age, immunocompromised or not, and primary series information Find Out When You Can Get Your Booster Boosters are an important part of protecting yourself from getting seriously ill or dying from COVID-19. They are recommended for most people.

e: CDC COVID-19

Use this tool to determine when or if you (or your child) can get one or more COVID-19

Find Out When to Get a Booster

NOVAVAX COVID-19 VACCINE

- Novavax Inc.'s adjuvanted COVID-19 vaccine
- First protein-based COVID-19 vaccine authorized in the U.S. .
- Two-dose primary series for those 12 years and older
 - 0.5 mL given intramuscularly 21 days apart (no dilution)
 - Store in the refrigerator and discard vial 6 hours after first puncture
- 2 myocarditis cases across 2 study populations during trials
 - Since the trial, Novavax has reported 35 spontaneous reports of potential myocarditis or pericarditis from a total of 744,000 doses given worldwide
- Unclear how it will perform against the Omicron variant
- An option for those who were hesitant to get an mRNA or viral vector based vaccine

MYOCARDITIS OR PERICARDITIS WITH MRNA VACCINE

- Precaution to a subsequent dose of any COVID-19 vaccine
 - If decision is made to receive another dose after risk assessment, wait until after the
 - episode has resolved
- Males ages 18 years and older
 - If want to receive a subsequent dose, Janssen may be considered instead of mRNA vaccines
- History of myocarditis or pericarditis unrelated to mRNA COVID-19 vaccination may receive any age-appropriate vaccine after the episode has resolved

Reference: CDC Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United State

JANSSEN VACCINE CONSIDERATIONS

- Guillain-Barré syndrome (GBS)
- A history of GBS is a precaution for Janssen vaccine (mRNA vaccine preferred)
- Those who develop GBS within 6 weeks of vaccination should only receive an mRNA vaccine for subsequent doses
- Thrombosis with thrombocytopenia syndrome (TTS)
 - Rare (~4 cases per one million doses administered)
 - Causes blood clots in large blood vessels and low platelets
 - Should receive a dose of an mRNA vaccine as a booster dose at least 2 months after Janssen vaccine and after condition has stabilized

Heparin-induced thrombocytopenia (HIT)

• History of an episode of spontaneous or classic HIT should receive an mRNA vaccine

Reference: CDC Interim Clinical Considerations for Use of COVID-15

Reference: Gavi.org

PRIOR OR CURRENT COVID-19 INFECTION

- Offer regardless of history of symptomatic/asymptomatic COVID-19 or exposure
- Viral or serologic testing to assess for prior infection is <u>not</u> recommended
- Defer vaccination in those with an active infection until recovered
 Those without any vaccine history OR
 - Those who are infected after the first dose of an mRNA vaccine
- May consider delaying primary series or booster by <u>3 months</u> from symptom onset or
 - positive test
- Vaccination is not recommended for post-exposure prophylaxis
- Vaccine can be given at <u>any interval</u> after receiving passive antibody therapy
 - Monoclonal antibodies or convalescent plasma

Reference: CDC Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United S

WHAT'S NEXT?

- Research and development for COVID-19 vaccines continues on
 - 137 COVID-19 vaccine candidates undergoing clinical trials and 194 candidates in preclinical development in January 2022
 - Some of the potential vaccine candidates undergoing trials include:
 - Oral bacterial vector vaccine that could have vaccine-like activity in the intestines
 - Intranasal vaccines
 - Self-amplifying nucleic acid vaccines
 - Many more

PATIENT CASE #2

A 16 year old male presents to your pharmacy with his mother and requests a COVID-19 vaccination prior to the upcoming school year. He is not immunocompromised.

• Which vaccine(s) is he eligible to receive?

After administering the vaccine, the patient's mother raises concerns about myocarditis that she heard about on the news.

How do you counsel the family?What dosing interval would you suggest to complete the series?

PATIENT CASE #2

Vaccine options:

- Moderna 2 dose series
- Pfizer 2 dose series
- Novavax 2 dose series
- Could also get Pfizer bivalent booster 2 months after completing primary series (regardless of which primary series is chosen)
 - Not Moderna since it's only approved for 18 years and older
 - No Novavax boosters currently available
- Cannot get J&J since he's not 18
 - Not a preferred option anyways

PATIENT CASE #2

- Myocarditis (inflammation of heart muscle) is a rare but serious potential side effect
- The benefits of getting the COVID-19 vaccination still outweigh the small potential risk of developing this condition
- Some studies have shown the small risk of myocarditis might be reduced and vaccine effectiveness may be increased with a longer interval between doses
- Recommend an 8-week interval since the patient is a male between the age of 12-39 and is not immunocompromised



SHINGRIX (ZOSTER VACCINE RECOMBINANT, ADJUVANTED)

Reference: GSK 2021, Hipper

- FDA approved for prevention of herpes zoster in those ≥18 who are or will be at an increased risk due to immunosuppression or immunodeficiency caused by a known therapy or disease
- Shorter vaccine schedule may be recommended in some cases

IMMUNOCOMPROMISED CONDITIONS FOR SHINGRIX

- Hematopoietic cell transplant (HCT) recipients
- Solid organ transplant recipients
- Patients with cancer
- Persons living with human immunodeficiency virus (HIV)
- Patients with autoimmune and inflammatory conditions

Reference: CDC Clinical Considerations for Use of Recombinant Zoster Vacc

HUMAN PAPILLOMAVIRUS (HPV)

- HPV is a very common virus that can cause cancers later in life
 - HPV is transmitted through intimate skin-to-skin contact with an infected person

Reference: CDC. Human Papillomavirus (HPV) Vaccination: What Everyone Should Know

 $\circ~~\sim\!\!36{,}000$ cancers are caused by HPV in the United States each year

HPV: BURDEN OF DISEASE

- HPV can cause cervical, vulvar, and vaginal cancer in females, penile cancer in males, and anal and oropharyngeal cancer in both females and males
 - HPV vaccination could prevent >90% of cancers caused by HPV from ever developing
 - This is an estimated 33,700 cases in the United States every year
- Cervical cancer is the only type of cancer caused by HPV with a recommended screening test for detection at an early stage
 - Other cancers may not be detected until they cause health problems

Reference: CDC. Human Papillomavirus (HPV) Vaccination Inform

| HPV causes cancers 5 to 20 years after infection | HPV Vaccine is expected to prevent cancers |
|---|---|
| Tongue & Tonsils: 10,000- 12,000 per year | 70% of tongue & tonsil cancers |
| Cervix: 10,000-12,000 per year | 90% of cervical cancers |
| Anus: 6,500 per year | 90% of anal cancers |
| Vaginal & Vulva: 3,500 per year | 40% of vaginal & vulvar cancers |
| Penis: 900 per year | 60% of penile cancers |
| | ###W.###p.:01g |
| | Reference: AAP HPV Fact Sheet |

HPV PREVENTION

The HPV vaccines are prophylactic and can be considered **CANCER PREVENTION**

- The vaccine does <u>not</u>:
 - Prevent progression of HPV infection to disease
 - Decrease time to clearance of HPV infection
 - Treat HPV-related disease
- HPV vaccination has resulted in significant declines in prevalence of vaccine-type HPV infections, anogenital warts, and cervical precancers

Reference: HPV-Imr

Reference: Merck.com-Gardasil9 par

HPV VACCINE: GARDASIL®9

- Inactivated 9-valent vaccine (9vHPV)
 - O Contains 7 cancer-causing HPV types (16, 18, 31, 33, 45, 52, and 58) • Two HPV types that cause most genital warts (6 and 11)
- Approved by the FDA in December 2014
 - Only HPV vaccine available in US market
- Licensed for females and males age 9 through 45 years

Reference: HPV-Immunize.org; Merck Va

avirus (HPV) ACIP Vaccine Red

HPV VACCINE

- HPV vaccine is not a "live" vaccine
- · Administration of a different inactivated or live vaccine is acceptable at the same visit
- Vaccine supplied as:
- Refrigerated vaccine
 Single-dose vial or prefilled syringe
- Dosage and administration:
- Each dose is 0.5 mL Intramuscular (IM) injection to the deltoid area is preferred

Side effects:

· Syncope; other reactions include injection site reaction (redness, swelling), headache, and fever

ACIP RECOMMENDATIONS FOR HPV VACCINE

- Routine HPV vaccination <u>initiated at age 11 or 12 years</u>
 - May be started as early as 9 years of age
- Also recommended for all people age 13 to 26 years who have not been vaccinated previously or who have not completed the vaccination series

Reference: Human Papillom

ACIP SCHEDULE FOR HPV VACCINE

For adolescents who start the vaccination series before the 15th birthday

• 2-dose HPV vaccine schedule is recommended

For all people who start the series on or after the 15th birthday and for people with <u>certain immunocompromising conditions</u> (such as cancer, HIV infection, or taking immunosuppressive drugs)

• 3-dose schedule is recommended



HPV & IMMUNIZE SD

"2 by 10" HPV Vaccination Project through ImmunizeSD • Project goal is to increase HPV vaccination rates in children aged 9 and 10 in South Dakota

 Strategies Provider education Community awareness
 Parents and guardians

More information at https://www.immunizesd.org



MONKEYPOX

Treatment

- No treatments specific for monkeypox Antivirals used to treat smallpox may be used
- Vaccination
 - Vaccines designed for smallpox may be used Routine vaccination for smallpox ended in 1970s

 - 2015 ACIP pre-exposure prophylaxis with ACAM2000 2022 ACIP JYNNEOS pre-exposure prophylaxis as an alternative to ACAM2000 for certain persons at risk for exposure to orthopoxyiruses
- Who should get vaccinated?
 - People who have been exposed to monkeypox or may be more likely to get monkeypox

Reference: CDC. Monkeypox ACIP - MMW

MONKEYPOX VACCINES

ACAM2000

- FDA approved for smallpox Does not contain smallpox virus, but a "live" vaccinia virus
- Special Considerations for Administration Two-pronged stainless steel (or bifurcated) needle is dipped into the vaccine solution and the skin is pricked several times in the upper arm with a droplet of the vaccine
 Virus begins growing at the injection site causing a localized infection or "pock" to form
- Side Effects and Considerations
 Contraindicated in pregnancy, immunocompromised, skin conditions
- Com balance in pregnatory, immonocompromised, sum continuous
 Can be "spread"
 Side effects: itching, sore arm, fever, headache, body ache, mild rash, fatigue, myocarditis/pericarditis
- Vaccine is **not** commercially available

Reference: CDC. Monkeypox. FDA. ACAm2000 package ins

MONKEYPOX VACCINES

JYNNEOS

- Dosage and Administration
 2 dose series; 0.5 mL per dose, 28 days apart
 Given subcataneously in the upper arm (deltoid)
 LIVE-attenuated vaccine
- Side Effects and Considerations

 - No severe adverse events in immunocompromised patients Should not receive if you have had allergic reaction after a previous dose, or have a history of allergic should not receive in you have had allergic reaction arrer a previous does, or have a nistary or allergic reaction to generatination, a profitoadian or chicken, long partetin Side effects: redness and liching at the spot where the vaccine is given as well as headache, tiredness, naurea, chills, and musice chief. Safer administration, no "special" needle necessary COVID-19 vaccines may be delayed by 4 weeks if the JYNNEOS vaccine is given first

 - - Reference: CDC. Monkeypox. FDA. J



VACCINES IN PREGNANCY

- No evidence of risk to the fetus from vaccinating pregnant women with inactivated virus or bacterial vaccines or toxoids
- Live vaccines pose a theoretical risk to the fetus
 - Live, attenuated virus and live bacterial vaccines generally are contraindicated during pregnancy
 - Live attenuated influenza vaccine (LAIV), MMR, Varicella
- MotherToBaby website has vaccine-related resources for those who are pregnant or

breastfeeding

INFLUENZA

- May receive any age-appropriate injectable flu vaccine regardless of thimerosal content
- Vaccination soon after vaccine becomes available may be considered during the third trimosto
 - Shown to reduce risk of influenza illness of their infants during the first months of life

Reference: CDC ACIP Recommend

COVID-19 AND PREGNANCY

- Growing body of evidence on the safety and effectiveness of COVID-19 vaccination shows the benefits of vaccination outweigh any known or potential risks during pregnancy
- V-Safe pregnancy registry did not find an increased risk of miscarriage with vaccination in early pregnancy
- No known evidence of fertility problems in men or women
- Acetaminophen should be recommended if a pregnant patient experiences a fever, for any reason, due to potential for adverse outcomes

Reference: CDC-COVID-19 Vaccines While Pregnant or Breastfeeding, ACOG, Mayo Clini

Reference: ACOG, MotherToBaby, CDC Guidelines for Vaccinating Pregnant V

COVID-19 AND BREASTFEEDING

- Vaccination is recommended by the CDC
 - Limited data on safety and effects of vaccination on milk production or babies
- COVID-19 vaccines cannot cause infection in the mother or their children • The vaccine is effective at preventing COVID-19 in mothers who are breastfeeding
- Mothers who received mRNA COVID-19 vaccines have been found to have antibodies
 - in their breast milk which could provide protection for babies • More data is needed to identify what protection may be provided
 - erence: CDC-COVID-19 Vaccines While Pregnant or Breast

TDAP

 CDC recommends all women receive a Tdap vaccine during the 27th through 36th week of each pregnancy

Reference: National Center for Immunization and Respiratory Di

- Preferably during the earlier part of this time period
- Protects against whooping cough, which can be deadly in infants

| Vaccine* | Indicated During Every Pregnancy | May Be Given During Pregnancy in Certain Populations | Contraindicated During Pregnancy | Can Be Initiated Postpartum or When Breastfeeding or Both |
|--|---|---|--|---|
| Inactivated influenza | X ^{†,1,2} | | | XI |
| Tetanus toxoid, reduced diphtheria toxoid and acellular pertussis (Tdap) | X ^{†,3,4} | | | X‡ |
| Pneumococcal vaccines | | X ^{5,5,6} | | X ^{5,5,6} |
| Meningococcal conjugate (MenACWY) and Meningococcal serogroup B | | X ^{,7} | | X ^{∥,7} |
| Hepatitis A | | X ^{1,8} | | X ^{1,8} |
| Hepatitis B | | X ^{#,9,10} | | X#,9,10 |
| Human papillomavirus (HPV)** | | | | X**, ^{11,12} |
| Measles-mumps-rubella | | | X ^{††,13,14} | X ^{††} |
| Varicella | | | X11,13,15,16 | X ^{††} |

PATIENT CASE #3

Patient is a 67 year old female with diabetes. She comes to your pharmacy asking if she is up-to-date on her vaccinations. When you look up her vaccine history in SDIIS, you see the following information:

| Influenza (Fluzone Quad) | 11/4/21 | | |
|--------------------------------|---------|----------|---|
| COVID-19 (Janssen) | 2/3/21 | 11/20/21 | ls she up to date on her vaccinations? |
| Tdap | 7/10/10 | | If not, which vaccine(s) do you |
| Shingrix | 4/12/21 | | recommend? |
| Zostavax | 2/10/10 | | |

PATIENT CASE #3

- COVID-19
 - Due for a booster
 Recommend a bivalent mRNA booster

Influenza

Recommend an enhanced influenza vaccine (if available)
 Fluzone HD, Fluad, Flublok

Pneumococcal

- Pneumococcal naive, over 65 years old, and has diabetes
 - PCV20 alone OR PCV15 followed by PCV23 given at least 1 year later

PATIENT CASE #3

• Tdap

- Update every 10 years
- Shingrix
- Due for second dose, no need to restart series
- Hepatitis B
 - Per updated recommendations, no screening required even if patient is not at high risk
 - Shared clinical decision-making



ADULT VACCINATION RATES IN THE U.S.

- Article published in May 2021 in the Morbidity and Mortality Weekly Report reviewed vaccination rates during certain time periods: o August 2017 to June 2018 for influenza vaccination o January 2018 to December 2018 for pneumcocccal, herpes zoster, tetanus, and diphtheria (Td/Tdap), hepatitis 8, and human papillomavirus (HPV) vaccination
- Coverage appears to have increased from 2010 to 2018 for most vaccines
- Engle uppedra 5 for the indexed indexed in the 20 for the index volutions volutions in Influenza (adults aged ≥19 years: 46%) Pneumococcal (adults aged ≥65 years: 69%) Herpes zoster (adults aged ≥19 years: 62.9%) Tadap (adults aged ≥19 years: 62.9%) Tadap (adults aged ≥19 years: 31.2%) Unartitle in tables aged ≥10 years: 31.2%)

 - Hepatitis A (adults aged ≥19 years: 12%) HPV (females aged 19-26 years: 53%)

Reference: Lu PJ, US Phan



VACCINE HESITANCY

- Hesitancy is not new
 - Has increased over the years due to many diseases being almost eradicated with the use of vaccinations
 - Emotional/cognitive response to assessment of risk/benefit of immunization
- COVID-19 vaccines are among the highest regarding hesitancy
 - Possibly causing more hesitancy to "spill" over to other vaccinations Vaccines for Children (VFC) program has noticed a decrease in vaccine order levels & childhood vaccination rates

Shixin (Cindy) Shen, Vinita Dubey: Addressing

VACCINE HESITANCY

- Can be an uncomfortable topic, not only with patients, but also family, friends, and colleagues
- Hesitancy has a broad spectrum
 - Attitudes towards vaccines fall on a continuum
 - Be prepared to adapt to different thoughts and modify conversations Important to target and address attitudes, social processes, motivation, and access and
 - other structural issues to nudge individuals toward vaccine acceptance

The more you try to insert information and advice into others,

the more they tend to back off and resist. Stephen Rollnick, co-founder of Motivational Interviewing





ADDRESSING VACCINE HESITANCY

- Start early (postnatal visits)
- Presenting vaccination as the default approach (presumptive)
- Build trust
 - Listen to & acknowledge concerns Provide education to help answer questions
 - Be honest about side effects & provide reassurance on vaccine safety (VAERS)
- Focus on protection of the child and community
- Facts or statistics may be presented
- Tell personal stories
 - Personal statements by healthcare professional and about what you would do for your own family/children Personal experiences with other patients

ce: Addressing Vac

COMMUNICATION APPROACHES

Presumptive vs. Participatory Approach

- Lead the conversation with a statement instead of a question
 Tell patients they need a vaccine(s)
 - Works well for most vaccinations, especially routine vaccinations or series vaccinations
 - Has increased vaccine acceptance rates when coming from HCP

"You need XYZ vaccine today" vs. "Do you want XYZ vaccine today?" "Today we are going to give you/your child the recommended

vaccines to keep you/your child healthy"

Reference: PMD, Addressing Vaccine H







BOOSTING VACCINATION RATES

Immunize at EVERY opportunity

- · Consider every patient encounter a potential vaccination opportunity
- Use reminder & recall systems
- Text messages, email, letters, postcards, and health system app(s)
- Implement standing orders
- Allow for assessment and vaccination of the patient by an authorized healthcare professional (phar clinician examination or direct order from provider at the time of interaction acist) without n Review patient vaccination history

Review your patient's immunization record (both your internal medical record and information available in the immunization registry) and flag the patient's profile/chart if your patient is due for vaccine(s)

Educate

Build trust in vaccines
 Vaccine-hesitant parents who are on the fence far outnumber vaccine refusers so counseling this group might be more effective

COADMINISTRATION OF VACCINES FOR ADULTS

- With a few rare exceptions, all vaccines can be administered at the same visit
- No upper limit for the number of vaccines that can be administered during a visit
- ACIP and AAP recommend that all needed vaccines be administered during a visit
 Vaccination should not be deferred because multiple vaccines are needed
- All live vaccines can be given at the same visit, if indicated
- MMR, varicella, live attenuated influenza, yellow fever, and oral typhoid
- If live vaccines are not administered during the same visit, they should be separated by at least 4 weeks

Reference: IAC, CDC Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States

COADMINISTRATION OF VACCINES FOR ADULTS

- When giving several injections at a single visit, separate IM vaccines by at least 1 inch if
 possible and document the location of each injection
- Administer the COVID-19 vaccines and vaccines that may be more likely to cause a local reaction in different limbs, if possible
 - Ex. tetanus-toxoid-containing and adjuvanted vaccines
- Consider implementing a vaccine screening form at your pharmacy to aid in identifying which vaccines a patient is eligible for when they present

Reference: IAC, CDC Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States



"CAN I STILL GET A VACCINE TODAY IF I HAVE A COUGH?"

- Administer vaccines to patients with mild acute illness
 - Avoid missed opportunities to vaccinate
 - Mild acute illness with or without fever is not a contraindication to vaccination
- Consider <u>delaying</u> vaccination with moderate to severe illness
- Vaccination side effects may make it difficult to assess management of acute illness
 <u>Delay</u> vaccination in those with suspected or confirmed COVID-19 infection
 - Wait until patients are no longer acutely ill to avoid exposing healthcare personnel and other patients
 - Remind patients to return for vaccination once recovered

Reference: CDC ACIP Recommendation

"CAN I STILL GET A VACCINE TODAY IF I'M ON AN ANTIBIOTIC?"

Reference: CDC Prevaccination Checkli

- People with mild illnesses can be vaccinated
- CDC specifically states not to withhold vaccination if a person is taking antibiotics

"HOW WILL MY PROVIDER KNOW I RECEIVED THIS VACCINE?" SDIIS South Dakota Immunization Information System

- Computer software system that allows health care providers to share immunization records
 O Cannot be accessed by the general public
- Pharmacies are not required to send a copy of vaccine records to providers
- Pharmacies are required to report all administered immunizations to SDIIS within 14 days
 of the immunization per South Dakota administrative rule

: SD Dep

nt of Health, SD Administ

18

"WHAT DO YOU MEAN I HAVE A COPAY?"

Vaccines Covered by Medicare Part B (no copay)

- COVID-19Influenza
- Pneumococcal
- Hepatitis B (if intermediate to high risk) Vaccines related to treatment of injury or direct exposure (tetanus, rabies)
- Vaccines Covered by Medicare Part D (may have a copay)
- Vaccines not covered by Part B, including:
 - Shingles

 - Tdap Hepatitis A (when medically necessary) Varicella (chicken pox)



PHARMACIST QUESTIONS

1. True or False: PCV13 continues to be recommended by the CDC as a routine pneumococcal vaccination for adults.

PHARMACIST QUESTIONS

False: It is now only recommended for use in all babies and children younger than 2 years old and children 2 through 18 years old with certain medical conditions.

PHARMACIST QUESTIONS

2. True or False: Egg allergy is a contraindication to receiving an influenza vaccination.

PHARMACIST QUESTIONS

2. False: Reported egg allergy is not a contraindication to flu vaccination.

PHARMACIST QUESTIONS

3. When addressing vaccine hesitancy using the "3 C's" (confidence, convenience, and complacency), confidence refers to:

- A. Access, affordability, and willingness to pay for vaccines and services
- B. Lack of trust in safety and efficacy of vaccine and/or competence of healthcare professionals, health system, and policy makers
- C. The perceived risk of disease is low, thus need to vaccinate is low
- D. A decision made on social responsibility

PHARMACIST QUESTIONS

3. B: Lack of trust in safety and efficacy of vaccine and/or competence of healthcare professionals, health system, and policy makers

PHARMACIST QUESTIONS

4. Which of the following are tools that can be used to verify which vaccinations an individual has already received?

- A. Online immunization information systems
- B. Electronic medical records
- C. Patient-reported vaccination history
- D. All of the above

PHARMACIST QUESTIONS

4. D: All of the above

TECHNICIAN QUESTIONS

 True or False: Only adults over the age of 65 are eligible to receive a pneumococcal vaccination.

TECHNICIAN QUESTIONS

 False: Pneumococcal vaccination, depending on which vaccine is used, is recommended for use in ages ranging from infants to elderly.

TECHNICIAN QUESTIONS

2. True or False: If you are 65 or older, you can receive a standard quadrivalent influenza vaccine.

TECHNICIAN QUESTIONS

2. True: The CDC continues to recommend vaccinating against the flu with any available flu vaccine. Any flu vaccine is better than no vaccination.

TECHNICIAN QUESTIONS

3. True or False: Vaccine hesitancy is a new issue facing healthcare today.

TECHNICIAN QUESTIONS

3. False: Vaccine hesitancy has existed for decades and will continue to be an obstacle for healthcare professionals.

TECHNICIAN QUESTIONS

4. Which of the following vaccinations is covered by Medicare Part D?

- A. Pneumococcal
- B. Hepatitis B
- C. Influenza
- D. Tdap

TECHNICIAN QUESTIONS

4. **D:** Tdap

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