## What's New with Flu, RSV, and COVID-19 Vaccines?

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## Outline

- Introduction
- Epidemiology
- Vaccines for Influenza, COVID-19, and RSV
- Addressing Patient Vaccine Concerns



## Introduction: HIV and Vaccines

- HIV causes defects in cell-mediated immunity, B-cell function, and antibody responses resulting in an increased risk of infections.
- Typical levels of protection after immunization:
  - Persons with advanced HIV: limited protection
  - Persons receiving HIV treatment: adequate protection
- Most vaccines are safe for people with HIV but:
  - Most live virus vaccines are contraindicated.
  - Some vaccines have special dosing recommendations.



### Immunization Recommendations for People with HIV

Vaccines	Recommended Schedules <sup>1</sup>	Additional Considerations
COVID-19	1 updated (2023–24) vaccine, regardless of prior vaccine history. See <u>COVID-19 Vaccine Timing Guide</u>	Advanced HIV infection: ≥ 1 updated vaccine(s). Additional doses based on clinical factors <sup>2</sup> .
Hepatitis A (HepA) <sup>3</sup>	Havrix <sup>®</sup> , Vaqta <sup>®</sup> : 2 doses, 6 months apart Twinrix <sup>®</sup> (HepA/HepB): 3 doses 0, 1, and 6 months apart	Check titers $\geq$ 1 month after series completion. If inadequate immune response, consider revaccination after CD4 $\geq$ 200 cells/mm <sup>3</sup> .
Hepatitis B (HepB) <sup>4</sup>	Engerix-B <sup>®</sup> , PreHevbrio <sup>®</sup> , Recombivax HB <sup>®</sup> : 3 doses 0, 1, and 6 months apart Heplisav-B <sup>®</sup> : 2 doses, 1 month apart Twinrix <sup>®</sup> (HepA/HepB): 3 doses, 0, 1, and 6 months apart	Consider double-dose strategy if using Engerix-B <sup>®</sup> or Recombivax HB <sup>®</sup> . Check titers $\geq$ 1 month after series completion. If inadequate immune response, consider revaccination after CD4 $\geq$ 200 cells/mm <sup>3</sup> .
Human papillomavirus (HPV)	Gardasil 9°: 3 doses, 0, 1-2, and 6 months apart for ages 15- 45 years	Not routinely recommended for ages 27–45 years but some people with HIV in this age range may benefit. Use shared clinical decision-making.
Influenza	<u>1 dose annually</u>	Live attenuated vaccine is contraindicated.
Measles, mumps, rubella (MMR)	M-M-R <sup>®</sup> II, Priorix <sup>®</sup> : 2 doses, 28 days apart <sup>5</sup>	Contraindicated if CD4 < 200 cells/mm <sup>3</sup> .
Meningococcal A, C, W, Y conjugate (MenACWY)	MenQuadfi <sup>®</sup> , Menveo <sup>®</sup> : 2 doses, 2 months apart; booster every 5 years	<u>Meningococcal cases increased</u> among people with HIV 2017–2022; vaccine coverage remains low.
Meningococcal B (MenB)	Bexsero <sup>®</sup> : 2 doses, 1 month apart Trumenba <sup>®</sup> : 2 or 3 doses, at 0, 1-2, and 6 months	Not routinely indicated for all adults with HIV. <sup>6</sup>
Mpox virus <sup>7</sup>	JYNNEOS®: 2 doses, 1 month apart	Can be given intradermally or subcutaneously.
Pneumococcal (PCV15, PCV20, or PPSV23)	Prevnar 20° (PCV20): 1 dose OR Vaxneuvance <sup>®</sup> (PCV15) + Pneumovax 23° (PPSV23): > 2 months apart	Consider <u>delay of PPSV23</u> until CD4 $\geq$ 200 cells/mm <sup>3</sup> .
Respiratory Syncytial Virus (RSV)	ABRSYVO®, AREXVY®: 1 dose	Not routinely recommended for all people with HIV; may be offered to people with HIV ages $\geq$ 60 years. Use shared clinical decision-making.
Tetanus, diphtheria, pertussis (Tdap/Td)	1 dose Tdap ( <b>Boostrix®, Adacel®)</b> , then Td <b>(Tenivac®</b> , <b>TDVAX®)</b> <i>OR</i> Tdap booster every 10 years	During each pregnancy, give one dose of Tdap. <sup>8</sup>
Varicella (VAR)	Varivax <sup>®</sup> : 2 doses, 28 days apart <sup>9</sup>	Contraindicated if CD4 < 200 cells/mm <sup>3</sup> .
Zoster (RZV)	Shingrix <sup>®</sup> : 2 doses for ages > 19 years, 2 months apart	Consider delay of Shingrix until CD4 > 200 cells/mm <sup>3</sup> .

#### Immunization Recommendations for Adults with HIV<sup>1</sup>

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IMM-1450 (9/23)

#### Immunization for Adults with HIV Job Aid



## HIV and the Vaccine Schedule

- HIV clinical care presents ongoing opportunities to address vaccination.
- Overall vaccination rates are good among people with HIV.
- Many opportunities for improvement; especially to address disparities by race/ethnicity.
- Vaccine fatigue and hesitancy is another important factor; can necessitate an in-depth conversation on the benefits of vaccination.

4.2. Receipt and Quality of HIV Care, Past 12 Months - Medical Monitoring Project, CA, 2020				
	Number <sup>a</sup>	Percentage <sup>b</sup>	95% Cl <sup>c</sup>	
Received Influenza Vaccination, Past 12 Months				
Yes	153	77.5%	71.5-83.4	

Behavioral and Clinical Characteristics of People Living with Diagnosed HIV in California 2020



## Overlapping Seasonality of Flu, COVID-19, and RSV

Weekly Rates of Respiratory Virus-Associated Hospitalizations in California, 2022-2023



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**CDC RESP-NET** 

CDC COVID Tracker

#### Influenza Season: 2022-23 Burden Estimates



2022-2023 U.S. Flu Season: Preliminary In-Season Burden Estimates | CDC



## All-Time COVID-19 Trends in California



## **RSV** Overview

- Common respiratory virus that usually causes mild, cold-like symptoms.
- Infants and older adults are more likely to develop severe RSV and need hospitalization.
- One of the most common causes of childhood illness and frequent cause of respiratory infections in older adults
- Lower awareness of RSV in adults among healthcare providers and the public
- RSV testing often not performed in adults
- No specific recommended treatment

<u>CDC RSV Informational Page</u> <u>CDC ACIP Meeting June 23, 2022 – Dr. Thornburg</u> Attachment (G) protein Fusion (F) protein Phosphoprotein (P) Matrix (M) protein Large polymerase (L) protein Lipid bilayer Nucleoprotein (N)



### Burden of RSV Hospitalization and Death Among Older Adults and Children <5 years



#### Adults aged ≥65 years

#### Children aged <5 years

<sup>1</sup>Falsey et al, NEJM (2005); <sup>2</sup>Adapted from Falsey et al, NEJM (2005); <sup>3</sup>Thompson et al, JAMA, 2003; <sup>4</sup>Hansen et al, JAMA Network Open, 2022; <sup>5</sup>Hall et al, NEJM, 2009; <sup>6</sup>McLaughlin et al, J Infect Dis, 2022

Havers presentation: ACIP June 23, 2022



### Similar Burden of RSV and Influenza Among Adults ≥65 years



<sup>1</sup>Falsey et al, NEJM (2005); <sup>2</sup>Adapted from Falsey et al, NEJM (2005); <sup>3</sup>Estimated Influenza Disease Burden 2015-2016 through 2019-2020, CDC (2022): https://www.cdc.gov/flu/about/burden/past-seasons.html

Havers presentation: ACIP June 23, 2022

### People with HIV and Flu, COVID-19, and RSV

- People with HIV have a higher risk of developing serious complications from influenza, COVID-19, and RSV.
- Vaccines can reduce risk of severe illness
  - Influenza and COVID-19 vaccines recommended for all adults, including people with HIV.
  - RSV vaccines now available for people with HIV who are 60 years and older.

Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023–24 Influenza Season Risk Factors for SARS-CoV-2 Infection and Severe Outcomes Among People With Human Immunodeficiency Virus Respiratory syncytial virus in adults with severe acute respiratory illness in a high HIV prevalence setting



### CDC 2023-24 Influenza Vaccine Guidance

Highlighted updates:

- 2023-24 Influenza Vaccine Composition
  - All vaccines are quadrivalent
  - All vaccines contain hemagglutinin derived from two A and two B viruses
- People with egg allergy may receive any influenza vaccine appropriate for their age and health status; additional safety measures are no longer recommended

Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023–24 Influenza Season

## Influenza Vaccine Reminders

- All persons 6 months of age and older are recommended to get an annual influenza vaccine.
- High-dose, adjuvanted, or recombinant influenza vaccines are preferred for adults ages 65 years and older. If none of these three vaccines is available, then any other ageappropriate influenza vaccine should be used.
- Live, attenuated influenza vaccine is contraindicated in people with HIV.
- September and October are the best times for most people to get vaccinated.







# CDC Recommends Updated 2023-2024 COVID-19 Vaccines for Everyone 6 Months and Older

- The 2023–2024 formulation of COVID-19 vaccines has been updated to a monovalent vaccine based on the Omicron XBB.1.5 sublineage of SARS-CoV-2
- Receiving an updated COVID-19 vaccine is safe and can restore protection against infections and severe disease
- Stop using formulations that are no longer authorized:
  - Bivalent mRNA COVID-19 vaccine (Original and Omicron BA.4/BA.5)
  - Novavax COVID-19 vaccine, adjuvanted (Original)

CDC Press Release 9/12/23 FDA Press Release 9/11/23 FDA Press Release 10/3/23 (Novavax)



### Variants and COVID-19 Vaccines

#### Weighted and Nowcast Estimates in United States for 2-Week Periods in 6/11/2023 – 9/30/2023



- EG.5 is now the dominant circulating variant and is an Omicron sublineage variant closely related to XBB.1.5
- 2023-2024 COVID-19 vaccine formulation contains XBB.1.5 variant and is expected to provide protection against EG.5.
- CDC also monitoring BA.2.86; recent laboratory data suggests vaccines will provide protection

<u>CDC Variant Tracker | World Health Organization, EG.5 Risk Evaluation 9/21/23</u> <u>Update on SARS-CoV-2 Variant BA.2.86 Being Tracked by CDC 9/15/23</u>



### **General Clinical Recommendations**

- Ages 6 months through 4 years
  - Unvaccinated: 2 doses of updated Moderna COVID-19 vaccine or 3 doses of updated Pfizer-BioNTech COVID-19 vaccine
  - Previously vaccinated: 1 or 2 doses of updated mRNA vaccine depending on number of previous doses
- Ages 5 years and older
  - Receive 1 dose of updated (2023–2024 Formula) mRNA COVID-19 vaccine, regardless of previous vaccination history
  - No additional doses recommended for people 65+ at this time
  - Guidance expected soon for updated Novavax COVID-19 vaccine

CDC Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States



#### Clinical Recommendations for Persons with Immunocompromise\*

- Persons with moderate or severe immunocompromise
  - Unvaccinated: People 6 months of age and older are recommended to receive 3 homologous doses of either updated Pfizer-BioNTech or Moderna COVID-19 vaccine
  - Previously vaccinated: 1 or 2 doses of updated mRNA vaccine depending on number of previous doses
  - May receive 1 or more additional updated mRNA COVID-19 vaccine doses, at least 2 months after their last COVID-19 dose

\*Description of moderate and severe immunocompromising conditions and treatment CDC Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States

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### Updated COVID-19 Vaccine Timing Guide 2023-2024



#### COVID-19 Vaccine Timing 2023-24 if Moderately/Severely Immunocompromised



#### **COVID-19 Vaccine Product Guide - Updated**

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#### **COVID-19 Vaccine Product Guide**

Check vaccine labels and <u>FDA materials</u> before use to avoid mix-ups. EUA fact sheets supersede info on vials and carton. Refer to <u>CDC Product Guide</u> for more information.

	Pfizer				
	Infant/Toddler 6 months-4 years	Pediatric 5-11 years	Comirnaty 12+ years		
	2023-24 Formula	2023-24 Formula	2023-24 Formula		
Packaging	Yellow Cap	Blue Cap	Gray Cap		
Doses Per Vial	3 doses	1 dose	1 dose		
Carton Size	30 doses	10 doses	10 doses		
NDC-Unit of Use (vial)	59267-4315-01	59267-4331-01	00069-2362-10		
CVX Code	302	301	300		
CPT Code	91318	91319	91320		
Program Availability	VFC	VFC	VFC, BAP		
Min. Standard Order*	30 doses	10 doses	10 doses		
Storage Limits Before P	imits Before Puncture: Label vaccine with expiration and use-by dates.				
ULT	Until expiration date at -90°C to -60°C (-130°F to -76°F)				
Thermal Shipper	٩				
Freezer	٩				
Refrigerator	Up to 10 weeks at 2° to 8°C (36°F to 46°F). Write the date on carton-not to exceed expiration.				
Expiration Date	Check	the label or Pfizer product v	vebsite.		
Administration					
Diluent (supplied)	1.1 mL per vial	Do not dilute	Do not dilute		
Dose Volume & Dose	0.3 mL 3 mcg dose	0.3 mL 10 mcg dose	0.3 mL 30 mcg dose		
Refrigerator Thaw Time (Do not refreeze)	2 hours in carton (2° to 8°C/36°F to 46°F)				
Room Temp Thaw Time (Do not refreeze)	Vial: 30 minutes at up to 25°C (77°F)				
Total Time at Room Temp	Up to 12 hours (including thaw time) at 8°C to 25°C (46°F to 77°F)				
Storage Limits After Pu	torage Limits After Puncture (Mult-dose vials): Record puncture and use-by time on vial label.				
Use-By Limit (Discard Time After 1st Puncture)	Discard 12 hours after dilution. Keep at 2°C to 25°C (35°F to 77°F)         N/A         N/A				
Orders for privately purcha	ased vaccines may have differe	nt order minimums.			
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#### COVID-19 Vaccine Product Guide

Check vaccine labels and FDA materials before use to avoid mix-ups. EUA fact sheets supersede info on vials and carton. Refer to CDC Product Guide for more information.

		Moderna		Novavax
	Pediatric 6 months 11 years	Spikevax 12+ years	Spikevax 12+ years	Adol/Adult 12+ years
	Green label 2023-24 Product	Blue label 2023-24 Product	2023-24 Product	2021 Product (new product coming soon)
Packaging	Dark Blue Cap	Dark Blue Cap	Syringe	Royal Blue Cap
Doses Per Vial	1 dose	1 dose	1 dose	5 doses
Carton Size	10 doses	10 doses	10 doses	50 doses
NDC-Unit of Use (vial)	80777-0287-07	80777-0102-04	80777-0102-01	80631-0102-01
CVX Code	311	312	312	211
CPT Code	91321	91322	91322	91304
Program Availability	VFC	VFC, BAP	TBD	TBD
Min. Standard Order*	10 doses	10 doses	TBD	TBD
Storage Limits Before	Puncture: Label va	ccine with expiration	n and use-by dates.	
JLT	۹ ۹			۲
Thermal Shipper	٩			۱
Freezer	Until expiration at -50°C to -15°C (-58°F to 5°F)			۱
Refrigerator	Up to 30 days (not to exceed expiration date) at 2–8°C (36-46°F) Until expiration			
Expiration Date	Check Moderna product website or QR code. Check product website.			
Administration				
Diluent (supplied)		Do not dilute		Do not dilute
Dose Volume & Dose	0.25 mL 25 mcg	0.5 mL 50mcg	0.5 mL 50mcg	0.5 mL 5 mcg
Refrigerator Thaw Time (Do not refreeze)	45 minutes for single dose vial or 1 hour for syringe at 2°C to 8°C (36°F to 46°F). Let stand at room temp for 15 min before administering.		N/A	
Room Temp Thaw Time (Do not refreeze)	15 minutes for single dose vial or 45 minutes for syringe at 15° to 25°C (59° to 77°F) N/A			
Total Time at Room Temp	Store up to 24 hours at 8°C to 25°C (46°F to 77°F)			
Storage Limits After P	uncture (Mult-dose	vials) Record use-by	time on vial.	
Use-By Limit (Discard Time After 1st Puncture)	N/A. Discard after single use. 25°C (36° to 77°F)			
Orders for privately purch	hased vaccines may ha	ve different order min	imums.	
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#### COVID-19 Vaccine Product Guide

#### **Do Not Use Deauthorized Products:**

Use only COVID-19 vaccine products updated for 2023-24

Pfizer						
Infant/T 6 months	oddler -4 years	Pedia 5–11 y	tric ears	A 1	dol/Adult  2+ years	
2021 Monovalent	Bivalent	2021 Monovalent	Bivalent	2021 Monovalent	Multi-dose	Single

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		Moderna		
Infant/Toddler 6 months- 5 years	Infant/Toddler 6 months– 5 years	6 months+	Pediatric 6-11 years	Adol/Adult 12+ years
Magenta Border 2021 Monovalent	Bivalent	Gray Border Bivalent	Purple Border 2021 Monovalent	Light Blue Border 2021 Monovalent



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#### COVID-19 Vaccine Product Guide

**California Department of Public Health, Immunization Branch** 

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## **RSV Prevention Products**

#### Adult Vaccines, ≥60 years

- **RSVPreF** (Abrysvo, Pfizer)
- **RSVPreF3 + Adjuvant** (Arexvy, GSK)

#### Infants and Young Children

- Nirsevimab (Beyfortus, Sanofi): monoclonal antibody for all infants and high-risk young children
- Palivizumab (Synagis, Sobi): monoclonal antibody for high-risk infants and young children
- RSVPreF (Abrysvo, Pfizer): prenatal vaccine at 32 to 36 weeks of pregnancy to protect infants



### Older Adult RSV Vaccine Recommendations

- Adults aged 60 years and older may receive a single dose of RSV vaccine, using shared clinical decision-making.
- Give as early as vaccine supply becomes available and continue to offer vaccination to eligible adults who remain unvaccinated.
- Co-administration of RSV vaccines with other adult vaccines during the same visit is acceptable.

<u>CDC RSV Media Statement June 29, 2023</u> <u>MMWR: Use of RSV Vaccines in Older Adults: ACIP Recommendations</u>



#### RSV Vaccines Approved for Adults Ages $\geq$ 60 Years

#### RSVPreF3 (Arexvy, GSK)

- RSV vaccine, adjuvanted
  - Antigen: 120ug RSVpreF3
  - Adjuvant: AS01E^
- 1 dose
- Intramuscular injection
- Efficacy: 82.6% reduction in risk of RSVassociated lower respiratory tract disease\*
- People with HIV excluded from trials

#### **RSVPreF (Abrysvo, Pfizer)**

- RSV vaccine, no adjuvant
  - Antigen: 60ug RSVpreF A and60ug RSVpreF B
- 1 dose
- Intramuscular injection
- Efficacy: 85.7% reduction in risk of RSVassociated lower respiratory tract disease\* with ≥3 symptoms
- People with well-controlled HIV included in trials, but data not yet available

\*Lower respiratory tract disease signs/symptoms include cough, sputum, and difficulty breathing. ^Similar to adjuvant used for Shingrix (half dose of same components)

AREXVY FDA Product Insert | ABRYSVO FDA Product Insert

## RSV Vaccines for Older Adults: Safety

#### RSVPreF3 (Arexvy, GSK)

- Safety:
  - injection site pain (60.9%)
  - fatigue (33.6%)
  - myalgia (28.9%)
  - headache (27.2%)
  - arthralgia (18.1%)
- Serious adverse events under monitoring:
  - Guillain-Barré Syndrome (GBS)
  - Acute disseminated encephalomyelitis (ADEM)
  - Supraventricular arrhythmias

#### **RSVPreF** (Abrysvo, Pfizer)

- Safety:
  - pain at the injection site (10.5%)
  - fatigue (15.5%)
  - muscle pain (10.1%)
  - headache (12.8%)
- Serious adverse events under monitoring:
  - Guillain-Barré Syndrome (GBS) and other immune-mediated demyelinating conditions
  - Supraventricular arrythmias



#### AREXVY FDA Product Insert | ABRYSVO FDA Product Insert

## Shared Clinical Decision-Making Guidance

- The decision to vaccinate should be based on a discussion between the provider and the patient, which might be guided by:
  - the patient's risk for disease and their characteristics, values, and preferences
  - the provider's clinical discretion
  - the characteristics of the vaccine.
- Consider factors associated with severe RSVassociated disease:
  - chronic medical conditions
  - frail or who are of advanced age\*
  - Residents of nursing homes and long-term care facilities\*

\*limited enrollment of these populations in clinical trials

<u>MMWR: Use of RSV Vaccines in Older Adults: ACIP Recommendations</u> <u>ACIP Shared Clinical Decision-Making Recommendations: Frequently Asked Questions</u>







#### **RSV Vaccine for Pregnant People**

- On 9/22/2023, members of CDC's Advisory Committee on Immunization Practices (ACIP) voted to recommend Pfizer's bivalent RSVpreF vaccine (trade name Abrysvo) for prevention of RSV lower respiratory tract infection in infants
- Indication
  - For use in pregnant people between **32 through 36 weeks gestation**
  - Seasonal administration between September through January
- The vaccine was approved for the Vaccines for Children (VFC) program for pregnant people under 19 years of age

#### <u>CDC ACIP Meeting Sept 22, 2023</u> <u>CDC Press Release</u>



### **Clinical Considerations**

- RSVpreF vaccine may be simultaneously administered with other indicated vaccinations in pregnancy
- <u>Either</u> vaccination during pregnancy or use of nirsevimab in the infant is recommended to prevent RSV lower respiratory tract infection in infants, but administration of both products is not needed for <u>most</u>.
- Healthcare providers of pregnant people should provide information on both products and consider patient preferences when determining whether to vaccinate the pregnant patient or to not vaccinate and rely on administration of nirsevimab to the infant after birth



#### **Assess For Other Needed Vaccines**

Even during respiratory virus season, it's still a good time to review and ensure your patients are up-to-date with their vaccines.

Vaccines	Recommended Schedules <sup>1</sup>	Additional Considerations
COVID-19	1 updated (2023–24) vaccine, regardless of prior vaccine history. See <u>COVID-19 Vaccine Timing Guide</u>	Advanced HIV infection: ≥ 1 updated vaccine(s). Additional doses based on clinical factors <sup>2</sup> .
Hepatitis A (HepA) <sup>3</sup>	Havrix <sup>®</sup> , Vaqta <sup>®</sup> : 2 doses, 6 months apart Twinrix <sup>®</sup> (HepA/HepB): 3 doses 0, 1, and 6 months apart	Check titers $\geq$ 1 month after series completion. If inadequate immune response, consider revaccination after CD4 $\geq$ 200 cells/mm <sup>3</sup> .
Hepatitis B (HepB) <sup>4</sup>	Engerix-B <sup>®</sup> , PreHevbrio <sup>®</sup> , Recombivax HB <sup>®</sup> : 3 doses 0, 1, and 6 months apart Heplisav-B <sup>®</sup> : 2 doses, 1 month apart Twinrix <sup>®</sup> (HepA/HepB): 3 doses, 0, 1, and 6 months apart	Consider double-dose strategy if using Engerix-B <sup>®</sup> or Recombivax HB <sup>®</sup> . Check titers $\geq$ 1 month after series completion. If inadequate immune response, consider revaccination after CD4 $\geq$ 200 cells/mm <sup>3</sup> .
Human papillomavirus (HPV)	Gardasil 9°: 3 doses, 0, 1-2, and 6 months apart for ages 15- 45 years	Not routinely recommended for ages 27–45 years but some people with HIV in this age range may benefit. Use shared clinical decision-making.
Influenza	<u>1 dose annually</u>	Live attenuated vaccine is contraindicated.
Measles, mumps, rubella (MMR)	M-M-R <sup>®</sup> II, Priorix <sup>®</sup> : 2 doses, 28 days apart <sup>5</sup>	Contraindicated if CD4 < 200 cells/mm <sup>3</sup> .
Meningococcal A, C, W, Y conjugate (MenACWY)	MenQuadfi <sup>e</sup> , Menveo <sup>e</sup> : 2 doses, 2 months apart; booster every 5 years	Meningococcal cases increased among people with HIV 2017–2022; vaccine coverage remains low.
Meningococcal B (MenB)	Bexsero <sup>®</sup> : 2 doses, 1 month apart Trumenba <sup>®</sup> : 2 or 3 doses, at 0, 1-2, and 6 months	Not routinely indicated for all adults with HIV. <sup>6</sup>
Mpox virus <sup>7</sup>	JYNNEOS®: 2 doses, 1 month apart	Can be given intradermally or subcutaneously.
Pneumococcal (PCV15, PCV20, or PPSV23)	Prevnar 20° (PCV20): 1 dose OR Vaxneuvance <sup>®</sup> (PCV15) + Pneumovax 23° (PPSV23): > 2 months apart	Consider delay of PPSV23 until CD4 $\geq$ 200 cells/mm <sup>3</sup> .
Respiratory Syncytial Virus (RSV)	ABRSYVO®, AREXVY®: 1 dose	Not routinely recommended for all people with HIV; may be offered to people with HIV ages $\geq$ 60 years. Use shared clinical decision-making.
Tetanus, diphtheria, pertussis (Tdap/Td)	1 dose Tdap ( <b>Boostrix<sup>®</sup>, Adacel<sup>®</sup>)</b> , then Td <b>(Tenivac<sup>®</sup>,</b> <b>TDVAX<sup>®</sup>)</b> <i>OR</i> Tdap booster every 10 years	During each pregnancy, give one dose of Tdap. <sup>8</sup>
Varicella (VAR)	Varivax <sup>®</sup> : 2 doses, 28 days apart <sup>9</sup>	Contraindicated if CD4 < 200 cells/mm <sup>3</sup> .
Zoster (RZV)	Shingrix <sup>®</sup> : 2 doses for ages > 19 years, 2 months apart	Consider delay of Shingrix until CD4 > 200 cells/mm <sup>3</sup> .
CDDLL		

Immunization Recommendations for Adults with HIV<sup>1</sup>

CDPH California Department of Public Health | Immunization Brand

IMM-1450 (9/23)



#### Vaccination for Adults with HIV Job Aid

### Mpox (Monkeypox) Vaccination Reminders



- Encourage patients at-risk of mpox infection to complete 2-dose series
- Gay, bisexual, or other same-gender loving man who has sex with men or are transgender, gender non-binary, or gender-diverse.
- Persons with HIV are at particular risk for severe mpox
- <u>Recent California study</u> shows that <u>></u> 1 dose of JYNNEOS vaccine for mpox reduces hospitalization risk
  - No cases of mpox in people with HIV that received 2 JYNNEOS doses (compared to 181 in unvaccinated persons with HIV)



### Make a Strong Recommendation

- Start with the **presumptive approach** 
  - Assumes the patient will choose to vaccinate
  - Your strong recommendation is the **most important part** of the vaccine conversation
- **Example**: "I see you're due for flu, COVID-19, and RSV vaccines today. As my patient, I strongly recommend these vaccines to protect you and others around you from serious illness. Let's get this ready for you now."

Immunization Strategies for Healthcare Practices and Providers (CDC) Talking with Patients about COVID-19 Vaccination (CDC)

## Motivational Interviewing

- For patients with vaccine concerns, consider applying motivational interviewing.
- There are **four steps** to apply motivational interviewing rapidly:
  - 1. Be empathetic
  - 2. Ask permission
  - 3. Apply interviewing techniques
  - 4. Respond to questions

Wolicki, JoEllen. "Talking to Patients about Vaccines" CDC COCA Call. Sept. 19, 2023.

Talking with Patients about COVID-19 Vaccination (CDC)





- Be compassionate and show empathy; be curious about the reasons they feel the way they do
- Be **sensitive** to culture, family dynamics, and circumstances that may influence how patients view vaccines.
- Do **not** argue or debate.

Wolicki, JoEllen. "Talking to Patients about Vaccines" CDC COCA Call. Sept. 19, 2023

## Step 2: Ask Permission

- Start by **asking permission** to discuss vaccines.
  - *"If it is okay with you, I would like to spend a few minutes talking about vaccines that are an important part of your care"*
- If the patient says they do **NOT** want to talk about vaccines:
  - Ask **why** they don't want to talk about vaccines:
    - "Can you tell me more about the reasons you don't want to discuss vaccination today?"
  - **Respect** the patient's decision
  - Ask if they would be willing to talk about vaccines at their next visit

Wolicki, JoEllen. "Talking to Patients about Vaccines" CDC COCA Call. Sept. 19, 2023.

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## **Step 3:** Apply Interviewing Techniques

- Open the conversation
  - Use open-ended questions to explore
  - Avoid yes/no questions
- Affirm positive behaviors
  - "That's great that you've gotten your flu vaccine. Now let's talk about some other vaccines."
- Reflect what you hear
  - "It sounds like you have some concerns."
- Summarize the conversation
  - "Let me see if I understand what you've said so far..."



## **Step 3:** Apply Interviewing Techniques

- Example: Ask the patient a scaled question.
  - "On a scale of 1 to 10, how likely are you to get a COVID-19 vaccine?"
- Keep exploring and reflectively listen.
  - "Why did you choose this number?"
  - "Why wasn't it lower/higher?"
  - "What would it take to get to a higher number?"
- The goal is to help the patient become more open to moving toward high numbers (i.e., to increase readiness to get vaccinated).



## Step 4: Respond to Questions

- If the patient asks a question about vaccine safety, vaccine risks, or their health or mental health, respond within the boundaries of your competence and scope of practice.
- Most data on safety and risk is population based. Practice reframing safety as individual risk.
  - *"Based on your health, you are at an increased risk of getting very sick, and in the group the vaccine will most benefit."*
- If you do not know the answer to a question, discuss how to find a good source of information.

## **CLINICAL SCENARIO AND DISCUSSION**





PowerPoint Stock Image

Manuel is a 64-year-old man with a history of hypertension, diabetes, chronic obstructive pulmonary disease (COPD) and HIV infection on ART (CD4 count >200) who comes for a routine appointment.

"I really don't want to get sick this winter. I heard about the new RSV vaccine at the grocery store. Should I get it? Should I get my flu shot too?"



## Should I get the RSV vaccine?

#### • Guidance

- RSV vaccines are now available for adults 60 years and older
- Shared clinical decision to receive the RSV vaccine
- Considerations
  - He has multiple risk factors for severe RSV disease
  - Vaccine efficacy and safety
  - Patient preferences







### Co-administration and Vaccine Timing

- Flu and COVID-19 vaccines also recommended.
- Healthcare providers can co-administer the vaccines for which a patient is eligible in the same visit.
- When deciding whether to co-administer other vaccines with RSV vaccine at the same visit, consider:
  - Is the patient up to date with currently recommended vaccines?
  - Feasibility of their returning for additional vaccine doses?
  - Risk of acquiring vaccine-preventable disease?
  - Vaccine reactogenicity profiles
  - Patient preferences





"Hmm...that's too many vaccines. I don't think my body can take it."

PowerPoint Stock Image



## Motivational Interviewing

For Manuel's vaccine concerns, consider applying **motivational interviewing**.

- 1. Be empathetic
- 2. Ask permission
- 3. Apply interviewing techniques
  - "It sounds like you have some concerns about getting more than one vaccine at a time."
- 4. Respond to questions
  - "Based on your age and health conditions, you are at an increased risk of getting very sick, and I strongly recommend flu and COVID-19 vaccines."

## Summary

- Everyone 6 months and older should receive an annual influenza vaccine and stay up to date on COVID-19 vaccines.
- People 60 years and older may receive RSV vaccine based a discussion with their healthcare provider
- Prenatal RSV vaccine is recommended at 32 to 36 weeks of pregnancy
- Influenza, COVID-19, and RSV vaccines can be co-administered.
- Motivational interviewing can support effective conversations with patients who have vaccine concerns.



### Vaccine Confidence Resources

- Vaccine Confidence Resources (CDPH)
- Vaccinate with Confidence (CDC)
- <u>Talking with Patients about COVID-19</u> <u>Vaccination (CDC)</u>
- Addressing Vaccination Anxiety in Adolescents and Adults (Immunize.org)



Getty Images, Gerber86



### Influenza Vaccine Resources

- Influenza Vaccine ID Guide (Updated for 2023-24)
- Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — U.S., 2023–24 Influenza Season (CDC)
- Flu and Respiratory Disease Prevention Resources (CDPH)
- Seasonal Influenza Resource Center (CDC)





#### **COVID-19 Vaccine Resources**

- <u>COVID-19 Vaccine Timing Tool</u> | <u>Spanish</u>
- <u>COVID-19 Vaccine Product Guide</u>
- Interim Clinical Considerations for Use of COVID-19 Vaccines in the U.S.
- <u>Respiratory Viruses Page</u> (CDC)
- <u>COVID-19, Flu, and RSV Page</u> (FDA)



### **RSV Vaccine Resources**

- <u>Healthcare Provider RSV Vaccine Page (CDC)</u>
- <u>Shared Clinical Decision-Making Guidance</u> <u>Flyer for RSV Vaccine (CDC)</u>
- <u>Use of RSV Vaccines in Older Adults:</u> <u>Recommendations of the Advisory</u> <u>Committee on Immunization Practices —</u> <u>U.S., 2023</u>
- <u>RSV Vaccine Information Statement (VIS)</u>

#### Shared Clinical Decision-Making (SCDM) RSV Vaccination for Adults 60 Years and Older

 Respiratory syncytial virus (RSV) is a cause of severe respiratory illness across the lifespan. Each year in the United States, RSV leads to approximately 60,000-160,000 hospitalizations and 6,000-10,000 deaths among adults 65 years and older.

 Adults 60 years of age and older now have the option to receive one dose of RSV vaccine based on a SCDM process between a patient and their health care provider.

Consider multiple factors when discussing RSV vaccination with your patients. SCDM recommendations are
optional and are informed by whether the patient has any risk factors for severe RSV disease; a patient's
risk of exposure to RSV; a patient's preferences for RSV vaccination; and the clinical discretion of the health
care provider.

#### Underlying medical conditions associated with increased risk for severe RSV disease include:





### More Provider Resources

- MPOX Vaccination Resources
- <u>Vaccination-Related</u>
   <u>Syncope</u> (Immunize.org)
- <u>Guidelines for the Prevention</u> and Treatment of Opportunistic <u>Infections in Adults and</u> <u>Adolescents with HIV</u> (NIH)
- More Resources

Vaccines	Recommended Schedules <sup>1</sup>	Additional Considerations
COVID-19	1 updated (2023–24) vaccine, regardless of prior vaccine history. See <u>COVID-19 Vaccine Timing Guide</u>	Advanced HIV infection: ≥ 1 updated vaccine(s). Additional doses based on clinical factors <sup>2</sup> .
Hepatitis A (HepA) <sup>3</sup>	Havrix <sup>®</sup> , Vaqta <sup>®</sup> : 2 doses, 6 months apart Twinrix <sup>®</sup> (HepA/HepB): 3 doses 0, 1, and 6 months apart	Check titers $\geq$ 1 month after series completion. If inadequate immune response, consider revaccination after CD4 $\geq$ 200 cells/mm <sup>3</sup> .
Hepatitis B (HepB) <sup>4</sup>	Engerix-B <sup>®</sup> , PreHevbrio <sup>®</sup> , Recombivax HB <sup>®</sup> : 3 doses 0, 1, and 6 months apart Heplisav-B <sup>®</sup> : 2 doses, 1 month apart Twinrix <sup>®</sup> (HepA/HepB): 3 doses, 0, 1, and 6 months apart	Consider double-dose strategy if using Engerix-B <sup>®</sup> or Recombivax HB <sup>®</sup> . Check titers $\geq$ 1 month after series completion. If inadequate immune response, consider revaccination after CD4 $\geq$ 200 cells/mm <sup>3</sup> .
Human papillomavirus (HPV)	Gardasil 9°: 3 doses, 0, 1-2, and 6 months apart for ages 15- 45 years	Not routinely recommended for ages 27–45 years but some people with HIV in this age range may benefit. Use shared clinical decision-making.
Influenza	1 dose annually	Live attenuated vaccine is contraindicated.
Measles, mumps, rubella (MMR)	M-M-R <sup>®</sup> II, Priorix <sup>®</sup> : 2 doses, 28 days apart <sup>5</sup>	Contraindicated if CD4 < 200 cells/mm <sup>3</sup> .
Meningococcal A, C, W, Y conjugate (MenACWY)	MenQuadfi <sup>®</sup> , Menveo <sup>®</sup> : 2 doses, 2 months apart; booster every 5 years	Meningococcal cases increased among people with HIV 2017–2022; vaccine coverage remains low.
Meningococcal B (MenB)	Bexsero <sup>®</sup> : 2 doses, 1 month apart Trumenba <sup>®</sup> : 2 or 3 doses, at 0, 1-2, and 6 months	Not routinely indicated for all adults with HIV. <sup>6</sup>
Mpox virus <sup>7</sup>	JYNNEOS®: 2 doses, 1 month apart	Can be given intradermally or subcutaneously.
Pneumococcal (PCV15, PCV20, or PPSV23)	Prevnar 20° (PCV20): 1 dose OR Vaxneuvance <sup>®</sup> (PCV15) + Pneumovax 23° (PPSV23): > 2 months apart	Consider delay of PPSV23 until CD4 $\geq$ 200 cells/mm <sup>3</sup> .
Respiratory Syncytial Virus (RSV)	ABRSYVO®, AREXVY®: 1 dose	Not routinely recommended for all people with HIV; may be offered to people with HIV ages $\geq$ 60 years. Use shared clinical decision-making.
Tetanus, diphtheria, pertussis (Tdap/Td)	1 dose Tdap ( <b>Boostrix<sup>®</sup>, Adacel<sup>®</sup>)</b> , then Td <b>(Tenivac<sup>®</sup>, TDVAX<sup>®</sup>)</b> <i>OR</i> Tdap booster every 10 years	During each pregnancy, give one dose of Tdap. <sup>8</sup>
Varicella (VAR)	Varivax <sup>®</sup> : 2 doses, 28 days apart <sup>9</sup>	Contraindicated if CD4 < 200 cells/mm <sup>3</sup> .
Zoster (RZV)	Shingrix <sup>®</sup> : 2 doses for ages > 19 years, 2 months apart	Consider delay of Shingrix until CD4 > 200 cells/mm <sup>3</sup> .

Immunization Recommendations for Adults with HIV<sup>1</sup>

CDPH California Department of Public Health | Immunization Branch

IMM-1450 (9/23)



Vaccination for Adults with HIV Job Aid

#### **More Patient Resources**

- <u>Vaccines for Men Who Have</u> <u>Sex with Men (MSM)</u> (Immunize.org)
- If You Have HIV/AIDS, Take Care of Yourself. Get a Flu Shot poster (CDC)
- <u>Make a Statement This Flu</u> <u>Season poster (CDC)</u>



#### Vaccine Poster for PWH

#### **Thriving with HIV?**



Place your logo or clinic info in box above. Delete this text before saving or printing. Tetanus, Diphtheria, Pertussis (Whooping Cough) (Tdap)

IMM-1456 (5/23)



## Thank you!

#### **Questions?**



Unsplash (2021)



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### **EXTRA SLIDES**



### Influenza Treatment

- Antiviral treatment is recommended as soon as possible for any patient with suspected or confirmed influenza who:
  - is <u>hospitalized;</u>
  - has severe, complicated, or progressive illness; or
  - is at higher risk for influenza complications.
- Decisions about starting antiviral treatment for patients with suspected influenza should not wait for laboratory confirmation of influenza virus infection.
- Clinicians can consider early empiric antiviral treatment of non-highrisk outpatients with suspected influenza [e.g., influenza-like illness (fever with either cough or sore throat)] based upon clinical judgement, if treatment can be initiated within 48 hours of illness onset.

Influenza Antiviral Medications: Summary for Clinicians (CDC)



#### **COVID** Treatment

 Most adults and some children are at risk of serious complications from COVID-19 and should be treated if symptomatic.

Unvaccinated	Obesity BMI >30
Physical Inactivity	Chronic pulmonary (including
Smoking	asthma), cardiac, renal, liver
Age <1 year and 10–14 years	diseases
and >50 years	Neurologic disorders
Prematurity (in young infants)	Diabetes
Non-White race/ethnicity	Immunocompromise

- Treatment is the ONLY way to reduce the risk serious outcomes after COVID-19 infection
- May also reduce the risk of Long COVID
- 40-89% risk reduction\* for hospitalization or death regardless of vaccination status

\*Comparison: Statins to prevent MI: 29% RRR Glycemic control to prevent microvascular endpoints: 25% RRR





## Outpatient COVID treatment – adult and pediatric

- Treatment by default
  - For all symptomatic patients >50 years old within 5 or 7 days of symptom onset
  - For high risk, symptomatic patients ≥12 years old within 5 or 7 days of symptom onset
  - Nirmatrelvir with ritonavir (Paxlovid) PO bid x5 days initiated within 5 days of symptom onset
    - Renal function and liver tests are **not required** ok to use clinical judgement, history, context
    - Test result not required
    - Check for <u>drug interactions</u>; very few absolute contraindications
    - Dose reduction in CKD
    - Standing Paxlovid orders with RN assessment are acceptable
  - **Remdesivir (Veklury)** IV daily x 3 days initiated within 7 days of symptom onset
    - Baseline labs: GFR, liver function, and prothrombin time tests
    - Not to be used in patients with GFR  $\leq$  30 mL/min

NIH Treatment Guidelines



#### COVID-19 Therapeutics Myths and Facts

How to dispel misinformation about treatments

#### MYTH:

I don't need medication for a mild-to-moderate illness.

#### **PROVIDER ANSWER:**

Lots of us are used to waiting out similar cold and flu symptoms to see if they get "bad enough" to need treatment. COVID-19 is different: lots of us are still at risk of having our mild or moderate symptoms develop into something more serious. The treatments can keep you out of the hospital and prevent you from dying, and early evidence shows they may even reduce your chance of developing long COVID.

#### MYTH: I'm not high risk.

#### **PROVIDER ANSWER:**

Most of us don't think of ourselves as "high risk." However, there are many factors that can make even very healthy people more susceptible to becoming very ill from COVID-19. The truth is: the majority of adults fit into one of these categories. They include:

- 1. Anyone over age of 50.
- People living with diabetes, mental conditions (anxiety, depression, ADHD, and more), chronic lung disease (including asthma), chronic kidney disease, and cardiovascular disease.
- 3. People who are overweight, physically inactive, or who smoke.
- People who are negatively affected by social determinants of health, such as race, ethnicity, socio-economic status, or limited access to healthcare.
- People who are unvaccinated or not up-to-date with vaccinations.



Scan the QR code to read more about COVID-19 treatment resources. CDPH Children of Children of the

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#### **COVID-19 Therapeutics Myths and Facts:**

#### MYTH:

Treatments have serious side effects.

#### **PROVIDER ANSWER:**

Of course, we all worry about side effects! Fortunately, most people have little-tono side effects. In clinical studies of Paxlovid, side effects occurred for less than 10% of patients. The most common side effect of Paxlovid is an unpleasant taste in the mouth, which occurred for 6% of people; smaller percentages of people have experienced diarrhea (3%), hypertension (1%), and/or muscle aches (1%).

Abdominal pain and general malaise have also been noted outside of clinical studies. Some other medications may need to be adjusted while you are taking Paxlovid. If you cannot take Paxlovid for any reason, you may be offered molnupiravir (Lagevrio) instead. Molnupiravir has very few side effects, but you cannot take it if you are pregnant.

#### MYTH: Rebound caused by treatments is common and can be dangerous.

#### **PROVIDER ANSWER:**

Rebound has been in the news a lot! The thing that most people don't realize is that viral rebound happens in people who don't take treatments as well as those who do, and less than 1 in 5 people experience rebound. It does happen somewhat more frequently among people who take Paxlovid. For some people, taking Paxlovid will help you test negative sooner. But for some, the symptoms may return. The good news is that if your symptoms do return, they tend to be mild and do not require repeating the treatment.

#### HELPFUL RESOURCES FOR PROVIDERS:

- COVID-19 Therapeutics Decision Aid (hhs.gov)
- Underlying Medical Conditions Associated with Risk for Severe COVID-19 | CDC
- Information Sheet: Paxlovid Eligibility and Effectiveness (hhs.gov)
- Have questions? Email COVIDRxProviders@cdph.ca.gov





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**Therapeutics Myths and Facts** 

## Recent COVID-19 Trends in California



#### Key metrics now focused on disease severity and system impact

CA COVID-19 Dashboard (Updated 9/22/23)

