### 2023 Update on Immunization Recommendations for Individuals With and At-Risk for HIV Disease

Denise H. Benkel, MD, MPH

Medical Specialist Bureau of Immunization

New York City Department of Health and Mental Hygiene



This activity is jointly provided by Physicians' Research Network and the Medical Society of the State of New York.

#### **Presentation Objectives**

- Be aware of the current recommendations for vaccines in individuals with and at-risk for HIV disease.
- Understand strategies to increase immunization and immunization acceptance.
- Know where to find up-to-date immunization recommendations on the web from reputable sources.



#### HIV and Vaccine-Preventable Diseases

- PLWH have defects in cell-mediated immunity, B-cell dysfunction, and suboptimal humoral immune responses
  - Antibody responses to vaccines are often less robust
- Vaccination is most effective in people with early HIV infection and those on ART who are virologically suppressed and have restored CD4 function
- Advisory Committee on Immunization Practices (ACIP) schedules, for children/adolescents and adults, include recommendations by "medical indication"
- One of the medical indications is HIV infection with CD4 counts:
  - <15% or total CD4 cell count of <200/mm<sup>3</sup>
     ≥15% and total CD4 cell count of ≥200/mm<sup>3</sup>



# (ACIP)

- 15 experts who are voting members
  - 14 have experts in vaccinology, immunology, pediatrics, internal medicine, nursing, family medicine, virology, public health, infectious diseases, or preventive medicine
  - 1 is a consumer representative who provides perspectives on the social and community aspects of vaccination
- 30 non-voting representatives from professional organizations who comment on ACIP recommendations
- Holds meetings at least three times each year
  - Workgroups active all year
- CDC publishes the U.S. adult and childhood immunization schedules based on ACIP recommendations



#### See Addendum for new or updated ACIP vaccine recommendations

 Table 1
 Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2023

These recommendations must be read with the notes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars.

To determine minimum intervals between doses, see the catch-up schedule (Table 2). 12 mos 15 mos 18 mos 19-23 mos 2-3 yrs 4-6 yrs 7-10 yrs 11-12 yrs 13-15 yrs Vaccine Birth 1 mo 2 mos 4 mos 6 mos 9 mos 16 yrs 17–18 yrs Hepatitis B (HepB) 1# dose ----- 2<sup>nd</sup> dose --3<sup>nd</sup> dose Rotavirus (RV): RV1 (2-dose series), RV5 (3-dose series) 1<sup>st</sup> dose See Notes 2<sup>nd</sup> dose Diphtheria, tetanus, acellular pertussis (DTaP <7 yrs) 2<sup>nd</sup> dose 3<sup>rd</sup> dose 5<sup>th</sup> dose 1<sup>st</sup> dose ▲3<sup>rd</sup> or 4<sup>th</sup> dose, See Notes Haemophilus influenzae type b (Hib) 2<sup>nd</sup> dose See Note 1<sup>st</sup> dose Pneumococcal conjugate (PCV13, PCV15) 1" dose 2<sup>nd</sup> dose 3<sup>rd</sup> dose ◄----- 4<sup>th</sup> dose -----▶ Inactivated poliovirus (IPV <18 yrs) 4<sup>th</sup> dose 1<sup>st</sup> dose 2<sup>nd</sup> dose 3<sup>nd</sup> dose Note COVID-19 (1vCOV-mRNA, 2vCOV-mRNA, 1vCOV-aPS) 2- or 3- dose primary series and booster (See Notes) Influenza (IIV4) Annual vaccination 1 dose only Annual vaccination 1 or 2 doses or or Annual vaccination Influenza (LAIV4) Annual vaccination 1 dose only 1 or 2 doses Measles, mumps, rubella (MMR) See Notes ◄----- 1<sup>st</sup> dose -----► 2<sup>nd</sup> dose Varicella (VAR) ◄----- 1<sup>#</sup> dose -----▶ 2<sup>nd</sup> dose Hepatitis A (HepA) See Notes 2-dose series, See Notes Tetanus, diphtheria, acellular pertussis (Tdap ≥7 yrs) 1 dose See Human papillomavirus (HPV) Notes Meningococcal (MenACWY-D ≥9 mos, MenACWY-CRM ≥2 mos, MenACWY-TT ≥2years) See Notes 1ª dose 2<sup>nd</sup> dose See Notes Meningococcal B (MenB-4C, MenB-FHbp) Pneumococcal polysaccharide (PPSV23) See Notes Seropositive in endemic Dengue (DEN4CYD; 9-16 yrs) dengue areas (See Notes) Range of recommended Range of recommended ages Range of recommended ages Recommended vaccination Recommended vaccination based No recommendation/ ages for all children for catch-up vaccination for certain high-risk groups can begin in this age group on shared clinical decision-making not applicable



Source: Birth-18 Years Immunization Schedule – Healthcare Providers | CDC

#### Notes

COVID-19 vaccination recommendations have changed. Find the latest recommendations at www.cdc.gov/covidschedule Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2023

For vaccination recommendations for persons ages 19 years or older, see the Recommended Adult Immunization Schedule, 2023.

#### Additional information

- Consult relevant ACIP statements for detailed recommendations at www.cdc.gov/vaccines/hcp/acip-recs/ index.html.
- For calculating intervals between doses, 4 weeks = 28 days. Intervals of ≥4 months are determined by calendar months.
- Within a number range (e.g., 12–18), a dash (–) should be read as "through."

 Vaccine doses administered s4 days before the minimum age or interval are considered valid. Doses of any vaccine administered 25 days earlier than the minimum age or minimum interval should not be counted as valid and should be repeated as age appropriate. The repeat dose should be spaced after the invalid dose by the recommended minimum interval. For further details, see Table 3-2, Recommended and minimum ages and intervals between vaccine doses, in General Best Practice Guidelines for Immunization at www.cdc.gov/vaccines/hcp/ acip-recs/general-recs/timing.html.

 Information on travel vaccination requirements and recommendations is available at www.cdc.gov/travel/.

 For vaccination of persons with immunodeficiencies, see Table 8-1, Vaccination of persons with primary and secondary immunodeficiencies, in General Best Practice Guidelines for Immunization at www.cdc.gov/vaccines/hcp/acip-recs/ general-recs/immunocompetence.html, and Immunization in Special Clinical Circumstances (In: Kimberlin DW, Barnett ED, Lynfield Ruth, Sawyer MH, eds. Red Book: 2021–2024 Report of the Committee on Infectious Diseases. 32<sup>ma</sup> ed. Itasca, IL: American Academy of Pediatrics; 2021:72–86).

 For information about vaccination in the setting of a vaccine-preventable disease outbreak, contact your state or local health department.

 The National Vaccine Injury Compensation Program (VICP) is a no-fault alternative to the traditional legal system for resolving vaccine injury claims. All vaccines included in the child and adolescent vaccine schedule are covered by VICP except dengue, PPSV23, and COVID-19 vaccines. COVID-19 vaccines that are authorized or approved by the FDA are covered by the Countermeasures Injury Compensation Program (CICP). For more information, see www.hrsa.gov/ vaccinecompensation or www.hrsa.gov/cicp.

#### COVID-19 vaccination (minimum age: 6 months [M

(minimum age: 6 months [Moderna and Pfizer-BioNTech COVID-19 vaccines], 12 years [Novavax COVID-19 Vaccine])

#### **Routine vaccination**

#### • Primary series:

- Age 6 months-4 years: 2-dose series at 0, 4-8 weeks (Moderna) or 3-dose series at 0, 3-8, 11-16 weeks (Pfizer-BioNTech)
- Age 5–11 years: 2-dose series at 0, 4-8 weeks (Moderna) or 2-dose series at 0, 3-8 weeks (Pfizer-BioNTech)

 - Age 12–18 years: 2-dose series at 0, 4-8 weeks (Moderna) or 2-dose series at 0, 3-8 weeks (Novavax, Pfizer-BioNTech)

 For booster dose recommendations see www.cdc. gov/vaccines/covid-19/clinical-considerations/interimconsiderations-us.html

#### Special situations

#### Persons who are moderately or severely immunocompromised

#### Primary series

- Age 6 months–4 years: 3-dose series at 0, 4, 8 weeks (Moderna) or 3-dose series at 0, 3, 11 weeks (Pfizer-BioNTech)
- Age 5-11 years: 3-dose series at 0, 4, 8 weeks (Moderna) or 3-dose series at 0, 3, 7 weeks (Pfizer-BioNTech)
- Age 12–18 years: 3-dose series at 0, 4, 8 weeks (Moderna) or 2-dose series at 0, 3 weeks (Novavax) or 3-dose series at 0, 3.7 weeks (Pfizzer-BioNTech)

 Booster dose: see www.cdc.gov/vaccines/covid-19/clinicalconsiderations/interim-considerations-us.html

 Pre-exposure prophylaxis (monoclonal antibodies) may be considered to complement COVID-19 vaccination. See www.cdc.gov/vaccines/covid-19/clinical-considerations/ interim-considerations-us.html#immunocompromised

For Janssen COVID-19 Vaccine recipients see COVID-19 schedule at www.cdc.gov/vaccines/covid-19/clinicalconsiderations/interim-considerations-us.html

Note: Administer an age-appropriate vaccine product for each dose. Current COVID-19 schedule and dosage formulation available at www.cdc.gov/vaccines/covid-19/downloads/ COVID-19-immunization-schedule-ages-6months-older. pdf. For more information on Emergency Use Authorization (EUA) indications for COVID-19 vaccines, see www.fda.gov/ emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines.

#### **Dengue vaccination**

(minimum age: 9 years)

#### **Routine vaccination**

 Age 9–16 years living in areas with endemic dengue AND have laboratory confirmation of previous dengue infection
 3-dose series administered at 0, 6, and 12 months

 Endemic areas include Puerto Rico, American Samoa, US Virgin Islands, Federated States of Micronesia, Republic of Marshall Islands, and the Republic of Plau. For updated guidance on dengue endemic areas and pre-vaccination laboratory testing see www.cdc.gov/mmwr/volumes/70/rr/ rr7006a1.htm?s.cid=rr7006a1\_w and www.cdc.gov/dengue/ vaccine/hcp/index.html

 Dengue vaccine should not be administered to children traveling to or visiting endemic dengue areas.

#### Diphtheria, tetanus, and pertussis (DTaP) vaccination (minimum age: 6 weeks [4 years for Kinrix\* or Quadracel\*])

#### **Routine vaccination**

- 5-dose series at age 2, 4, 6, 15–18 months, 4–6 years
   Prospectively: Dose 4 may be administered as early as age
- 12 months if at least 6 months have elapsed since dose 3. - Retrospectively: A 4<sup>th</sup> dose that was inadvertently administered as early as age 12 months may be counted if at

least 4 months have elapsed since dose 3.

#### Catch-up vaccination

 Dose 5 is not necessary if dose 4 was administered at age 4 years or older and at least 6 months after dose 3.

For other catch-up guidance, see Table 2.

#### Special situations

 Wound management in children less than age 7 years with history of 3 or more doses of tetanus-toxoid-containing vaccine: For all wounds except Clean and minor wounds, administer DTaP if more than 5 years since last dose of tetanus-toxoid-containing vaccine. For detailed information, see www.cdc.gov/mwwr/volumes/67/rr/rfo202a1.htm.



#### Source: Birth-18 Years Immunization Schedule – Healthcare Providers | CDC

Table 3	Та	bl	e	3
---------	----	----	---	---

**Recommended** Child and Adolescent United States,

mmunization Schedule by Medical Indication,

#### Always use this table in conjunction with Table 1 and the Notes that follow.

	INDICATION									
VACCINE	Pregnancy	Immunocom- promised status (excluding HIV infection)	HIV infectio <15% or total CD4 cell count of <200/mm <sup>3</sup>	n CD4+ counta ≥15% and total CD4 cell count of ≥200/mm <sup>3</sup>	Kidney failure, end-stage renal disease, or on hemodialysis	Heart disease or chronic lung disease	CSF leak or cochlear implant	Asplenia or persistent complement component deficiencies	Chronic liver disease	Diabetes
Hepatitis B										
Rotavirus		SCID <sup>b</sup>								
Diphtheria, tetanus, and acellular pertussis (DTaP)										
Haemophilus influenzae type b										
Pneumococcal conjugate										
nactivated poliovirus										
COVID-19		See Notes	See	Notes						
nfluenza (IIV4)										
nfluenza (LAIV4)						Asthma, wheezing: 2–4yrs <sup>c</sup>				
Measles, mumps, rubella	*									
/aricella	*									
Hepatitis A										
letanus, diphtheria, and acellular pertussis (Tdap)										
Human papillomavirus	*									
Meningococcal ACWY										
Meningococcal B										
Pneumococcal polysaccharide										
Dengue										
Vaccination according to routine schedule recommended		Recommended for persons with an addition factor for which the var would be indicated	onal risk <b>en a</b> ccine r	Vaccination is recomm and additional doses necessary based on m condition or vaccine.	may be nedical See Notes.	Precaution-vaccine might be indicated if benefit of protection outweighs risk of adverse reaction	recommen be adminis "Vaccinate	after pregnancy	No recomm applicable	endation/not

a. For additional information regarding HIV laboratory parameters and use of live vaccines, see the General Best Practice Guidelines for Immunization, "Altered Immunocompetence," at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html and Table 4-1 (footnote J) at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.htm
 b. Severe Combined Immunodeficiency
 c. LAIV4 contraindicated for children 2-4 years of age with asthma or wheezing during the preceding 12 months



Source: <u>Birth-18 Years Immunization Schedule – Healthcare Providers | CDC</u>

Vaccine	Pregnancy	Immuno- compromised (excluding HIV infection)		tion CD4 and count ≥15% and ≥200 mm <sup>3</sup>	Asplenia, complement deficiencies	End-stage renal disease, or on hemodialysis	Heart or lung disease; alcoholism*	Chronic liver disease	Diabetes	Health care personnel <sup>b</sup>	Men whe have sex with me
COVID-19			See Notes								
IIV4 or RIV4					1	dose annually				or	
LAIV4		Cr ntraindicated							1 dose a	nually	
Tdap or Td	1 dose Tdap each pregnancy				dose Tdap, tl	hen Td or Tdap	booster every	10 years			
MMR	Contraindicated*	Contrain	licated	1 or 2 doses depending on indication							
VAR	Contraindicated*	Contrain	licated	2 doses							
RZV		2 dos	s at age ≥19 y	at age ≥19 years 2 doses at age ≥50 years							
HPV	Not Recommended*	3 doses 1	hrough age 2	ough age 26 years 2 or 3 doses through age 26 years depending on age at initial vaccination or co			dition				
Pneumococcal (PCV15, PCV20, PPSV23)				1 dose PCV15 followed by PPSV23 OR 1 dose PCV20 (see notes)							
НерА							2, 3, or 4 c	loses dependir	ng on vaccino	e	
НерВ	3 doses (see notes)				2, 3, or 4 dos	es depending	on vaccine or	condition			
MenACWY		1 or 2 dose	depending	depending on indication, see notes for booster recommendations							
MenB	Precaution		2 or 3 o	doses depend	ng on vaccine	and indication	n, see notes fo	r booster recon	nmendation	s	
Hib		3 doses HSCT <sup>c</sup> recipients only			1 dose						
Recommended va for adults who me age requirement, documentation of vaccination, or lac	et lack	Recommended vaco for adults with an ac risk factor or anothe indication	ditional	Recommended va based on shared o decision-making		Precaution-vaccin might be indicate benefit of protect outweighs risk of reaction	d if	Contraindicated or recommended-va should not be adm *Vaccinate after pr	ccine ninistered.	No recomment Not applicable	

a. Precaution for LAIV4 does not apply to alcoholism. b. See notes for influenza; hepatitis B; measles, mumps, and rubella; and varicella vaccinations. c. Hematopoietic stem cell transplant.



Source: Adult Immunization Schedule – Healthcare Providers | CDC

### Inactivated vs. Live Vaccines

- Inactivated vaccines generally safe and acceptable in individuals with HIV
  - Administration does not have to be delayed when CD4 count low or virologic suppression has not been achieved
  - Revaccination once immune restitution and virologic suppression has been achieved is recommended for certain vaccines
- Live vaccines should not be given to individuals with CD4 <15% or <200/mm<sup>3</sup>
  - Certain live vaccines are recommended in patients with CD4>15% and >200/mm<sup>3</sup>

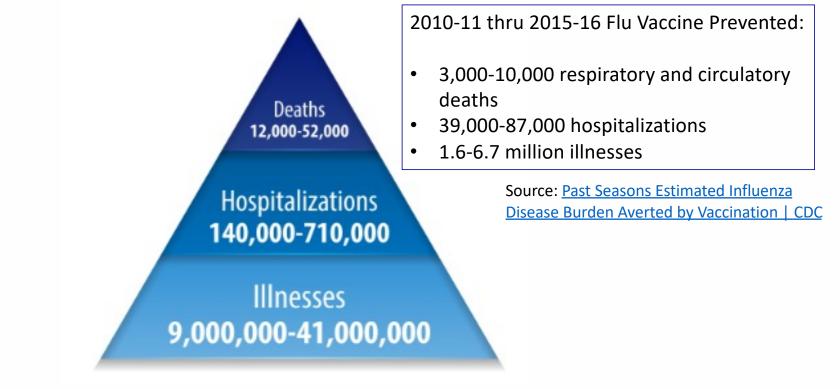


Adapted from: Immunizations in persons with HIV - UpToDate

### Influenza



# Estimated Range of Annual Burden of Influenza in U.S. 2010-2020





Source: https:/www.cdc.gov/flu/about/burden/index.html

### Flu Vaccine Rates

- U.S. Healthy People 2030 goal for flu vaccine is 70% for all ages
- U.S. flu vaccine coverage rate for 2021-2022<sup>1</sup>: 51.4%
- NYC flu coverage rate for 2022-2023 for 9-18 year-olds<sup>2</sup>: 36.6%
- NYC 2022 Community Health Survey of adults > 18 years<sup>3</sup>: 51.4%

https://www.cdc.gov/flu/fluvaxview/coverage-2022estimates.htm
 Unpublished data, NYC Citywide Immunization Registry, run on 8/23/23
 Unpublished Data, NYC Health Department, 2022 Community Health Survey



### Flu Vaccine Recommendations

- Influenza vaccination is recommended for <u>all</u> persons age 6 months and older
- Special emphasis on persons at highest risk for complications from influenza, and their contacts
- Children aged 6-59 months, especially < 2 years
- Adults <u>></u> 50, especially <u>></u> 65 years
- Children and adolescents < 19 years of age on long-term aspirin therapy
- Persons who are pregnant or will be pregnant during influenza season
- Residents of long-term care facilities
- American Indians and Alaskan Natives
- People with BMI > 40 kg/m2

- Chronic pulmonary disorders (including asthma)
- Cardiovascular diseases (except hypertension)
- Renal, hepatic, neurologic disease
- Hematologic, metabolic or endocrine disorders (including diabetes mellitus)
- Immunosuppression, including HIV-related or caused by medications or malignancy



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

### Flu Vaccine Recommendations

- Annual administration, preferably in September or October
- All inactivated flu vaccines may be used in PLWH
  - Do not use live, intranasal vaccine (FluMist)
- Several studies have demonstrated the efficacy and safety of flu vaccine in PLWH



### Inactivated Flu Vaccine Formulations

- Standard Dose, Egg-Based (IIV4)
  - Afluria, Fluarix, FluLaval, Fluzone
- Cell-cultured Standard Dose (cclIV4)
  - Flucelvax
- High-Dose, Egg-Based (HD-IIV4)
  - Fluzone High-Dose Quadrivalent (>65 years of age)
- Adjuvanted, Egg-Based (allV4)
  - Fluad Quadrivalent (>65 years of age)
- Recombinant (RIV4)
  - Flublok (>18 years of age)

Recommended for those age  $\geq$  65 years, but give any other if not available



### Flu Vaccine and Egg Allergy

- All persons with egg allergy can receive any influenza vaccine (eggbased or nonegg-based)
- No longer recommended that a person with egg allergy other than urticaria be vaccinated in an inpatient or outpatient medical setting supervised by a provider who is able to recognize and manage severe allergic reactions
- ALL vaccines should be administered in settings in which personnel and equipment needed for rapid recognition and treatment of acute hypersensitivity reactions are available



Source: Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices United States, 2023–24 Influenza Season | MMWR (cdc.gov)

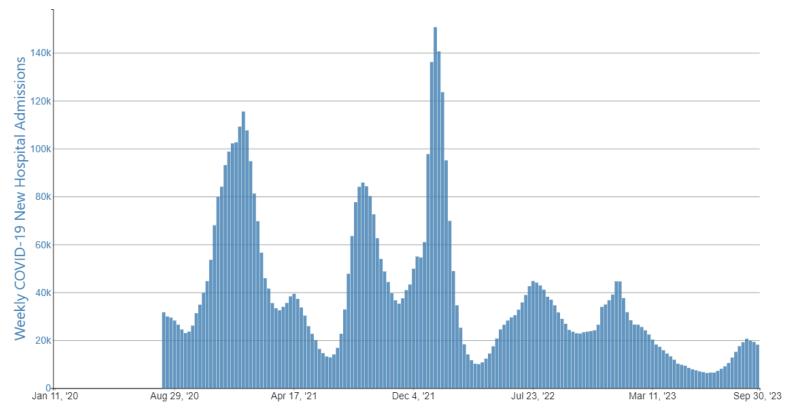
#### Responding to Patients' Flu Misconception: The Flu Vaccine Gave Me the Flu!

- Patient might have already been sick but not yet symptomatic at the time of vaccination
- Patient may have been infected with influenza after vaccination but before the vaccine had time to fully protect them
  - Takes 2 weeks after vaccination for full protection
- Influenza infections can happen from a strain(s) not included in vaccine
- Patient may have been infected with another virus or bacteria that cause symptoms similar to influenza
- No vaccine is 100% effective, but patient should be reassured it was not the flu vaccine that made them sick



### COVID-19





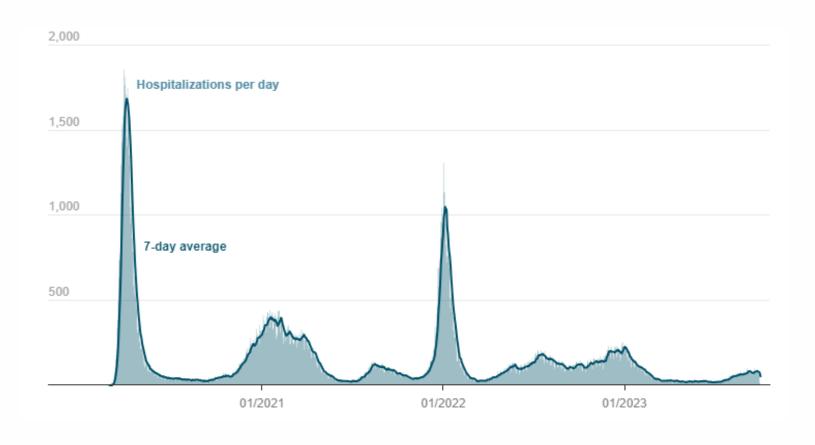
COVID-19 New Hospital Admissions, by Week, in The United States, Reported to CDC

Centers for Disease Control and Prevention. COVID Data Tracker. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2023, October 06. https://covid.cdc.gov/covid-data-tracker



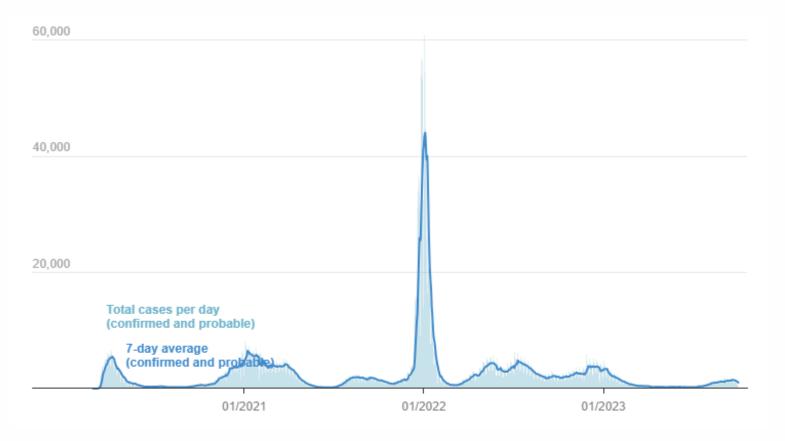
Source: <u>CDC COVID Data Tracker: Trends by Geographic Area</u> Accessed 10-6-2023

### New York City COVID-19 Hospitalizations





### New York City COVID-19 Cases





Source: COVID-19: Data Trends and Totals - NYC Health Accessed 10-6-2023

### Updated 2023-2024 COVID-19 Vaccines

- There are new Pfizer, Moderna, and Novovax vaccines
- They are monovalent vaccine, based on the Omicron XBB.1.5 sublineage of SARS-CoV-2
- The original monovalent and bivalent formulations should no longer be used.



## 2023-2024 COVID-19 Vaccine Recommendations for Persons >12 Years of Age NOT Moderately or Severely Immunocompromised, by Vaccine History

COVID-19 vaccination history prior to updated (2023–2024 Formula) vaccine*	Updated (2023– 2024 Formula) vaccine	Number of updated (2023–2024 Formula) doses indicated	Dosage (mL/ug)	Vaccine vial cap and label colors <sup>§</sup>	Interval between doses				
Unvaccinated	Moderna	1	0.5 mL/50 ug	Dark blue cap; blue label	_				
	OR								
	Novavax	2	0.5 mL/5 ug rS protein and 50 ug Matrix-M adjuvant	Blue cap; blue label	Dose 1 and Dose 2: 3–8 weeks <sup>+</sup>				
	OR								
	Pfizer-BioNTech	1	0.3 mL/30 ug	Gray cap; gray label	_				
1 or more doses any mRNA; 1 or more doses Novavax or Janssen, including in combination with any Original monovalent or bivalent COVID-19 vaccine doses	Moderna	1	0.5 mL/50 ug	Dark blue cap; blue label	At least 8 weeks after last dose				
			OR						
	Novavax	1	0.5 mL/5 ug rS protein and 50 ug Matrix-M adjuvant	Blue cap; blue label	At least 8 weeks after last dose				
	OR								
	Pfizer-BioNTech	1	0.3 mL/30 ug	Gray cap; gray label	At least 8 weeks after last dose				



Source: Clinical Guidance for COVID-19 Vaccination | CDC

### COVID-19 Vaccination in PLWH

- For those with a CD4>200/mm<sup>3</sup> and who are virologically suppressed on ART, the schedule is the same as for people without HIV
- Use schedule for people with moderate or severe immunocompromising conditions if the person has advanced HIV infection, i.e.,
  - CD4 <200/mm<sup>3</sup>
  - History of an AIDS-defining illness without immune reconstitution, or
  - Clinical manifestations of symptomatic HIV

Or if they have an untreated HIV infection



Source: Clinical Guidance for COVID-19 Vaccination | CDC

#### COVID-19 Vaccine Recommendations for persons >12 years of age who *are* moderately or severely

- immunocompromised
   Unvaccinated: 3 homologous (i.e., from the same manufacturer) updated mRNA vaccine doses OR 2 updated Novavax vaccine doses
  - Previously received 1 or 2 monovalent or bivalent mRNA vaccine doses: Complete the 3-dose series with 2 or 1 **homologous** updated mRNA vaccine doses, respectively
  - Previously received a combined total of 3 or more monovalent or bivalent mRNA vaccine doses: 1 dose of any updated COVID-19 vaccine
  - Previously received 1 or more monovalent Novavax vaccine doses, alone or in combination with any monovalent or bivalent mRNA vaccine doses: 1 dose of any updated COVID-19 vaccine
  - Previously received 1 or more doses of Janssen vaccine, alone or in combination with any monovalent or bivalent mRNA vaccine or monovalent Novavax doses: 1 dose of any updated COVID-19 vaccine
  - Additional doses: May receive 1 or more additional COVID-19 vaccine following the last recommended updated COVID-19 vaccine dose



Source: Clinical Guidance for COVID-19 Vaccination | CDC

### COVID-19 Vaccine MYTHS

• VAERS reports have shown few adverse events even *possibly* linked to vaccine

#### NONE OF THIS IS TRUE:

- Affects fertility
- Has microchips
- Alters DNA
- Is unsafe
- Causes variants



### Respiratory Syncytial Virus (RSV)



### Respiratory Syncytial Virus (RSV)

- RSV causes severe disease in persons with compromised immunity
- In May 2023, FDA approved first vaccines for prevention of RSVassociated LRTD in persons aged <u>></u>60 years
- Two vaccines:
  - RSVPreF3 (Arexvy, GSK)
  - RSVpreF (Abryso<sup>TM</sup>, Pfizer)
  - Just one dose (for now), after "shared clinical decision-making"
- Post-marketing surveillance for GBS required for both vaccines, after six patients of nearly 40,000 in clinical trials developed inflammatory neurologic events within 42 days of vaccination
  - At least 2 of these cases were likely GBS
  - Background rate of GBS is 1.85/100,000 for people in their 60s
  - Background rates of GBS is 2.66/100,000 for people in their 80s



Source: Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023 | MMWR (cdc.gov)

### RSV Vaccine Shared Clinical Decision-Making

- Recommendation doesn't target all persons in a particular age group or with an identifiable risk factor
- Allows flexibility for providers and patients to consider individual risk for RSV disease, while taking into account patient's preference
- Decision should be guided by:
  - Patient's risk for disease/severe disease
  - Patient's characteristics, values, and preferences
  - Provider's clinical discretion
  - Characteristics of the vaccine



Source: <u>Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on</u> <u>Immunization Practices — United States, 2023 | MMWR (cdc.gov)</u>

### **RSV Vaccine Co-Administration**

- Co-administration with other adult vaccines is "acceptable"
- Available data on immunogenicity of co-administration are currently limited
- Co-administration *might* increase local or systemic reactogenicity
- Post-licensure efficacy and safety monitoring of co-administered RSV vaccines with other vaccines will further direct guidance



Source: <u>Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on</u> <u>Immunization Practices — United States, 2023 | MMWR (cdc.gov)</u>

### **RSV Vaccine Co-Administration Decisions**

- Feasibility of patient returning for additional vaccines
- Likelihood patient will return for other vaccines
- Risk for acquiring other vaccine-preventable diseases that deferred vaccines protect against
- Vaccine reactogenicity profiles
  - Recombinant zoster vaccine and RSVPreF3 contain same adjuvant
- Patient preference



Source: <u>Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on</u> <u>Immunization Practices — United States, 2023 | MMWR (cdc.gov)</u>

### Other New RSV Immunization Products

- Monoclonal antibody product, nirsevimab, for infants < 8 months of age during RSV season—preferably within first week of life and children between 8 months and 19 months if at increased risk for severe RSV illness during their second RSV season
- RSV vaccine RSVPreF (Abrysvo) for pregnant persons during 32-36 weeks' gestation for protection in the infant
- Both pregnant person administration and infant administration not recommended, except in limited circumstances
  - One of those circumstances is if the birth parent is a PLWH since there is concern that there was not enough transplacental antibody transfer after the vaccine administration



### Pneumococcal Vaccines PCV15, PCV20, and PPSV23



## Pneumococcal Vaccine Recommendations for PLWH: <18 year of age

- For children aged 2–18 years who have received all recommended
  - doses of PCV before age 6 years
    - Using ≥1 dose(s) of PCV20: No additional doses of any pneumococcal vaccine are indicated
    - Using PCV13 or PCV15 (no PCV20): A dose of PCV20 or PPSV23
- For children aged 6–18 years who have not received any dose of PCV13, PCV15, or PCV20: a single dose of PCV15 or PCV20 is recommended. When PCV15 is used, it should be followed by a dose of PPSV23 at least 8 weeks later if not previously given.



Source: <u>Birth-18 Years Immunization Schedule – Healthcare Providers | CDC</u> ADDENDUM

#### Pneumococcal Vaccine Recommendations for PLWH: 19-64 years of age

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 yearst PPSV23 Review pneumococcal vaccine recommendations again when your patient turns 65 years old.
PCV13 and 2 doses of PPSV23	≥5 years PCV20	<b>No vaccines</b> 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 <sup>§</sup> Generalized malignancy     HIV infection     Hodgkin disease     latrogenic immunos     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

<sup>†</sup> The minimum interval for PPSV23 is ≥8 weeks since last PCV13 dose and ≥5 years since last PPSV23 dose

<sup>5</sup> Includes B- (humoral) or T-lymphocyte deficiency, complement deficiencies (particularly C1, C2, C3, and C4 deficiencies), and phagocytic disorders (excluding chronic granulomatous disease)

<sup>1</sup> Includes diseases requiring treatment with immunosuppressive drugs, including long-term systemic corticosteroids and radiation therapy



Source: https://www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf

#### Pneumococcal Vaccine Recommendations for PLWH: <a>> 65</a> years of age

Vaccine received previously at any age	Schedule option A (PCV20 available)	-	Schedule option B (PCV15 and PPSV23 available)		
None/unknown <sup>†</sup> or PCV7 only <sup>§</sup>	Administer a single dose of PCV20		Administer a single dose of PCV15, then after ≥8 weeks since the PCV15 dose, administer a single dose of PPSV23		
PPSV23 only <sup>§</sup>	Administer a single dose of PCV20 after a ≥1 year interval since the last PPSV23 dose		Administer a single dose of PCV15 after a ≥1 year interval since the last PPSV23 dose		
PCV13 only	Administer a single dose of PCV20 after a ≥1 year interval since the last PCV13 dose¶		Administer a single dose of PPSV23 after ≥8 weeks since the last PCV13 dose**		
Both PCV13 and PPSV23 (any order of receipt) but has not yet received a dose of PPSV23 at age ≥65 years	Administer a single dose of PCV20 after a ≥5 year interval since the last PCV13 or PPSV23 dose <sup>¶</sup>		Administer a single dose of PPSV23 after ≥8 weeks since the last PCV13 dose and ≥5 years since the last PPSV23 dose**		
Both PCV13 and PPSV23 (any order), and the PPSV23 was administered at age ≥65 years	Together, with the patient, vaccine providers may choose to administer a single dose of PCV20 to adults aged ≥65 years who already have received PCV13 (but not PCV15 or PCV20) at any age and PPSV23 at age ≥65 years. The interval should be ≥5 years since the last PCV13 or PPSV23 dose. ¶#		N/A		



Source: Pneumococcal Vaccine for Adults Aged ≥19 Years: Recommendations of the Advisory Committee on Immunization Practices, United States, 2023 | MMWR (cdc.gov) Table 2

## Мрох



## **Mpox Transmission**

- Although many of those affected in the current global outbreaks are MSM, the virus can be acquired by anyone who has been in close contact with someone with mpox
- The virus that causes mpox is transmitted via the following:
  - Direct skin-to-skin contact with an infectious rash, scabs, or body fluids
  - Exposure to respiratory secretions during prolonged face-to-face contact or intimate physical contact, such as kissing, cuddling, or sex
  - Touching objects or fabrics (e.g., clothing or linens) that have been in contact with the rash or body fluids of someone with mpox
  - Being scratched or bitten by an infected animal



## Who should get Mpox vaccine?

- People who had known or suspected exposure to someone w/mpox
- People who had a sex partner in the past 2 weeks who was diagnosed with mpox
- Gay, bisexual, and other MSM, and transgender or nonbinary people (including adolescents who fall into any of these 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; or
  - Sex in exchange for money or other items
- People who are sexual partners of people with the above risks
- People who anticipate experiencing any of the above scenarios
- People with HIV infection or other causes of immunosuppression who have had recent or anticipate potential mpox exposure
- People at risk during a mpox outbreak (as determined by public health)



Source: Vaccination Basics for Healthcare Professionals | Mpox | Poxvirus | CDC

## Mpox Vaccine

- JYNNEOS is the only available mpox vaccine that is considered safe for PLWH
- Is a live virus vaccine that does not replicate efficiently in human cells
- FDA approved for those age > 18 years of age and has EUA for those <18 years
- Can be used to prevent mpox and as post-exposure prophylaxis
  - If used as PEP vaccine might prevent development of symptoms or decrease severity of mpox disease
  - As PEP, best used within 4 days of exposure
  - If given 4-14 days after exposure may still reduce symptoms
- Can be given regardless of CD4 count or viral suppression
  - Efficacy may be lower in those with low CD4 counts but given the risk of severe illness in immunosuppressed individuals, vaccination is still recommended
- 2 doses 4 weeks apart
- Standard regimen is SQ



## Accessing Mpox Vaccine in NYC

- In NYC, it's through NYC DOHMH
- Email <a href="mailto:poxvax@health.nyc.gov">poxvax@health.nyc.gov</a>
- Have to enroll in Mpox program
  - Includes signing a provider agreement
  - 20-dose minimum
- Vaccine provided at no cost by the Federal government



## Hepatitis B



## Hepatitis B in PLWH

- PLWH are at increased risk of HBV infection due to shared modes of transmission
- PLWH are less likely to develop a protective immune response and be able to clear HBV DNA so at increased risk of chronic infection<sup>1,2</sup>
- PLWH who develop chronic HBV are at higher risk of developing cirrhosis, hepatocellular CA, and end-stage liver disease compared with those with chronic hepatitis b without HIV<sup>2</sup>



<u>1.Immunizations in persons with HIV</u> <u>- UpToDate</u> 2. <u>Prevention of hepatitis B virus</u> infection in adults with HIV - UpToDate

## HepB Vaccine in PLWH

- The antibody response to HepB vaccination is reduced in PLWH<sup>1</sup>
- If PWLH has h/o immunization check for hepatitis B antibodies to confirm immunity unless a seroprotective response has been previously documented<sup>2</sup>



2. <u>Immunizations in persons with HIV</u> - UpToDate

#### HepB Vaccine Recommendations

- Persons aged <19 years
- Persons aged 19-59 years
- Adults aged >60 years of age with risk factors for hepatitis B, including
  - Sexually active persons who are not in a long-term mutually monogamous relationship (persons with >1 sex partner in previous 6 months)
  - Persons seeking evaluation or treatment for an STI
  - MSM
  - Sex/household contacts of persons testing positive for HBsAg
  - Persons with hepatitis C infection
  - PLWH
  - Those aged >60 years without known risk factors may receive HepB vaccine



Source: <u>Universal Hepatitis B Vaccination in Adults Aged 19–59 Years: Updated Recommendations of the</u> <u>Advisory Committee on Immunization Practices — United States, 2022 (cdc.gov)</u>

## Hep B Vaccine Clinical Guidance

- Administer conventional recombinant Engerix-B or Recombivax HB according to routine schedule, at 0, 1 and 6 months
  - Heplisav if there's a concern patient won't return in 6 months
- Alternative administration strategies, such as 3- or 4-injection doubledose vaccination series or an accelerated schedule at 0, 1, and 3 weeks may be considered
- If accelerated schedule is used, a fourth booster should be administered <u>>6</u> months after initiation of the series
- Test for anti-HBs 1-2 months after administration of last dose
- Persons who do not respond to the primary HBV series should be revaccinated with Heplisav-B or a double-dose of the vaccine series previously administered (especially if single dose used initially)
- Experience with PreHevbrio in PLWH lacking



Source: Immunizations for Adults With HIV – Clinical Guidelines Program (hivguidelines.org)

## Hepatitis A (HepA)



#### HepA Vaccine Recommendations

- Risk for longer duration of hepA viremia in the setting of HIV
- Routine recommendation for all susceptible PLWH age > 1 year
- Can use regular HepA vaccines or formulation with HepB (Twinrix)
- Follow routine schedule
- Obtain HAV IgG testing >1 month after final dose to confirm immune response
- Patients who don't respond to primary series should be revaccinated and counseled to avoid exposure until fully vaccinated
- If vaccination occurred when CD4 count low, and immune reconstitution appears likely, consider deferring revaccination until patient's CD4 count <u>></u>200/mm<sup>3</sup>



Source: Immunizations in persons with HIV - UpToDate

## Tdap



#### **Tdap Vaccine Recommendations**

- Same as routine recommendations for people without HIV
- One dose for all individuals <a>>11</a> years of age
- Td or Tdap every ten years thereafter
- One Tdap with each pregnancy
- In general, immunogenicity appears somewhat lower and shorterlived than it is in the general population\*
  - Similar response to tetanus but diphtheria immunity is lower than expected
  - Among those with advance HIV, response to both tetanus and diphtheria is lower than expected since immune response is T cell-dependent



\*Immunizations in persons with HIV - UpToDate

## Polio



## Polio Vaccine

- Same recommendations as for people without HIV
- Most adults born in U.S. assumed to have been vaccinated as children and don't need further doses
- Adults who are known or suspected to be unvaccinated or incompletely vaccinated against polio should complete a primary vaccination series
- Adults at increased risk of poliovirus exposure may receive another dose
- Available data do not indicate the need for more than a single lifetime booster dose



## Haemophilus influenzae type B (Hib)



#### **Hib Vaccine Recommendations**

- Children aged 5-18 years LWH can receive a single dose of Hib vaccine if they have not already been vaccinated
- Hib is not specifically recommended for adults living with HIV unless there is another specific indication (e.g., asplenia)



## Human Papillomavirus (HPV)



## HPV

- Common STI
- HPV acquisition generally occurs soon after first sexual activity
- Most infections are transient
- Persistent infections with high-risk HPV types can lead to cervical, anal, penile, vaginal, vulvar and oropharyngeal cancers, usually after decades
  - 91% of cervical cancers
  - 70% of oropharyngeal cancers in U.S. caused by HPV



Source: How Many Cancers Are Linked with HPV Each Year? | CDC

#### **HPV Vaccine**

- If seeing adolescents, can start as early as 9 even though recommendation is for ages 11-12
- Recommendation is through age 26 years
  - Shared clinical decision-making for those 27-45 years
- Don't test before vaccination
- A history of genital warts—often caused by HPV—abnormal cytology, or positive HPV DNA test should not preclude vaccination
- Won't change the course of established infections
  - Can prevent infection by strains not yet exposed to
- Give 3 dose series, at 0, 2, and 6 months
  - Don't use 2-dose series, even if age <15 years



# Meningococcal Serotypes A, C, W, and Y (MenACWY)



#### MenACWY Vaccine Recommendations

- PLWH are at increased risk of invasive meningococcal disease due to serogroups C, W, and Y
  - Up to a 10-fold increased risk of invasive meningococcal disease in PWLH, with the highest risk among those with CD4 counts <200 cells/mm<sup>3</sup>
- Recommended for all PLWH
  - 2 dose series, 8 weeks apart
- Administer 1 booster of MenACWY every 5 years



Source: <u>Immunizations for Adults With HIV – Clinical Guidelines Program (hivguidelines.org</u>)

## Meningococcal Serotype B (MenB)



#### MenB Vaccine Recommendations

- Not routinely recommended for PLWH in the absence of other risk factors
- Recommended for patients at risk of gonorrhea infection, e.g., MSMs and other individuals who have had a bacterial STI in the prior 12 months, sex workers, and individuals engaging in condomless sex with multiple partners
- *N. gonorrhoeae* and *N. meningitidis* are genetically similar and share many outer membrane proteins
- MenB vaccination has been associated with 30% to 40% protection against gonorrhea
- Bexsero (4CMenB) and Trumenba (MenB-FHbp) not interchangeable



Source: Immunizations for Adults With HIV – Clinical Guidelines Program (hivguidelines.org)

## MMR



#### **MMR Vaccine Recommendations**

- For PLWH with CD4 counts <a>200</a> cells/mm<sup>3</sup> for <a>6</a> months who do not have evidence of MMR immunity
- Contraindicated if CD4 < 200/mm<sup>3</sup>
- Documentation of previous age-appropriate vaccination or positive serology are both acceptable evidence of immunity
- MMRV not studied adequately in PLWH population so don't use, even if child is age <12 years</li>
- No recommendation for post-vaccination testing
- In setting of mumps outbreak, give third dose to improve protection
  - Same recommendation as for persons without HIV



Source: Immunizations for Adults With HIV – Clinical Guidelines Program (hivguidelines.org)

## Varicella



## Varicella Vaccine Recommendations

- Administer to PLWH with CD4 counts <a>200</a> cells/mm<sup>3</sup> for <a>6</a> months who do not have evidence of varicella immunity
- Contraindicated if CD4 < 200/mm<sup>3</sup>
- Because of possibility of severe disease, providers should verify varicella immunity
  - Birth before 1980 not acceptable evidence
  - Anti-varicella IgG screening should be performed if no known h/o varicella or shingles, documentation of 2 doses of vaccine, or serologic evidence
- Antiherpetic agents should be avoided for <u>></u>24 hours before vaccination through 14 days after
- Post-vaccination testing is not recommended
- Don't use MMRV
- If (rare) clinical disease after vaccination, treat with acyclovir



Source: <u>Immunizations for Adults With HIV – Clinical Guidelines Program (hivguidelines.org</u>)

## Zoster



#### Zoster Vaccine Recommendations

- PLWH at increased risk of (initial episodes and recurrence of) zoster at all stages of HIV illness
  - Patients with advanced HIV especially at risk of shingles
- Administer 2 doses of recombinant zoster vaccine (RZV; Shingrix) to PLWH age <a>19 years</a>
- Anti-varicella IgG screening should be performed if no known h/o chickenpox or shingles and if screening negative, and CD4 >200, give varicella vaccination before zoster vaccination



Source: <u>Immunizations for Adults With HIV – Clinical Guidelines Program (hivguidelines.org</u>)

#### Strategies to Increase Immunization Rates

- Assess immunization status at preferably before each visit
- Avoid missed opportunities to vaccinate
- Make a clear, strong, and personalized recommendation
- Leverage immunization information system functionality, e.g., Decision Support, tools to run reminder/recall lists
  - Citywide Immunization Registry (CIR) in NYC
- Schedule the next immunization visit, if necessary before patient leaves
- Create a culture of immunization within the practice
  - Every practice member has a role
- Use standard orders when possible



## How to Handle Vaccine Resistance

- Engage the patient respectfully and fully in the discussion
- Use empathy, collaboration, elicitation (of their feelings), support for autonomy
- Use open-ended questions and reflections
- Use behavior-change principles like emphasizing social norms, pivoting from debunking myths to focus on the disease that is prevented



## Thank You for Your Attendance! Please visit us at: *www.prn.org*