

Ryan White Clinics: Preparing for the 2021-2022 Flu Season Amid a Pandemic

September 29, 2021



WELCOME!

Agenda

- Introduction
- Polling Questions
- Importance of Flu Vaccination
- Influenza Vaccination and HIV Update
- ADAP
- Qs & As, Discussion Questions
- Evaluation

Disclaimer

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Overall Learning Objectives

- Describe the reasons why influenza immunizations are especially important during the COVID-19 pandemic
- Gain knowledge on current guidance about COVID-19 variants and third mRNA COVID-19 vaccine for people with HIV
- List programs that can pay for influenza vaccine and administration for people with HIV



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Ryan White Clinics: Preparing for Flu Season in an Ongoing COVID-19 Pandemic

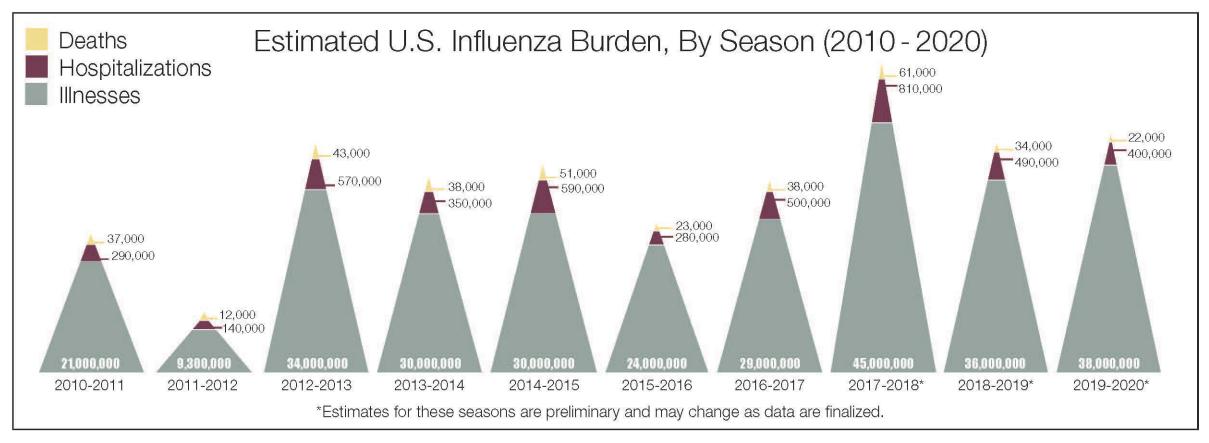
Lily Horng, MD MPH Immunization Branch Medical Officer California Department of Public Health September 29, 2021



Overview

- Why flu vaccination is important during the ongoing COVID-19 pandemic
 - Burden of influenza
 - Why flu vaccines are important during COVID-19
 - Timing of flu vaccines

Estimated Influenza Disease Burden, by Season United States, 2010-11 through 2019-20 Influenza Seasons



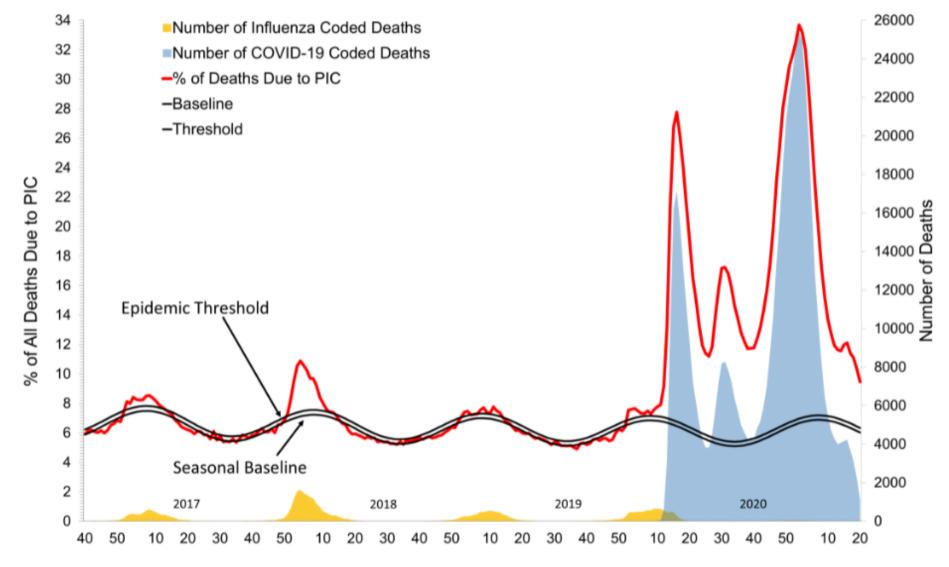
www.cdc.gov/flu/about/burden/index.html

2020-2021 Influenza Season

- Flu activity was unusually low throughout the 2020-2021 flu season.
- Possible reasons why?
 - COVID-19 mitigation measures such as wearing face masks, staying home, hand washing, school closures, reduced travel, increased ventilation of indoor spaces, and physical distancing, likely contributed to the decline in 2020-2021 flu incidence, hospitalizations and deaths.
 - Influenza vaccination may also have contributed to reduced flu illness during the 2020–2021 season. Flu vaccine effectiveness estimates for 2020-2021 are not available, but a <u>record number</u> of influenza vaccine doses (193.8 million doses) were distributed in the U.S. during 2020-2021.

Pneumonia, Influenza, and COVID-19 Mortality from the National Center for Health Statistics Mortality Surveillance System

Data through the week ending May 22, 2021, as of May 27, 2021



www.cdc.gov/flu/weekly/ weeklyarchives2020-2021/week20.htm

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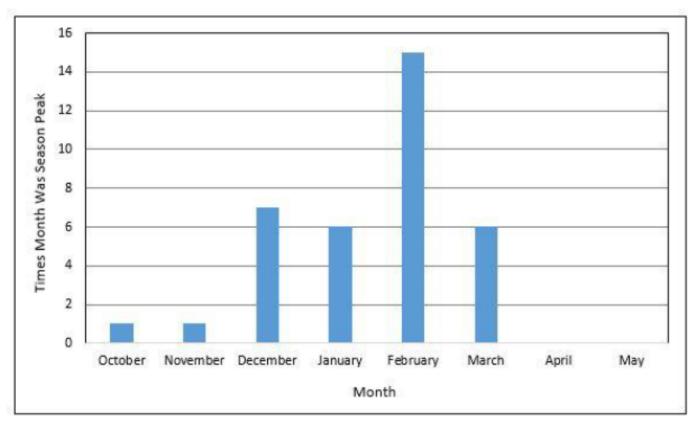
MMWR Week

Flu vaccines are critical this season

- Even if they are immunized against COVID-19, people are still vulnerable to flu if they have not received a flu vaccine. Flu can even be life threatening.
- Flu and COVID-19 symptoms are similar.
 - Delays in diagnosis can lead to delays in treatment.
 - For those working outside their homes, this could mean missing days of work until it's OK to go back.
 - Adults at high risk for severe flu illness are also high risk for severe COVID-19.
- Combination of COVID-19 pandemic and seasonal flu epidemic will stress health system.

Timing of Influenza Seasons

- Timing of the onset and peak of influenza activity varies from season to season.
- Timing of activity onset can also vary geographically.
- In the United States, localized areas of increased activity occur as early as October.
- Over the 36 seasons between 1982-83 and 2017-18, peak activity occurred in:



December

7 (19%) seasons

January

6 (17%) seasons

February

15 (42%) seasons

March

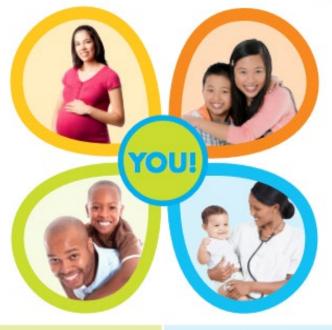
6 (19%) seasons

https://www.cdc.gov/flu/about/season/flu-season.htm

https://emergency.cdc.gov/coca/ppt/2021/090921_slide.pdf

Who should get a flu vaccine?





Everyone **6 months of age and older** needs a flu vaccine every year. Ask us about getting one today!

Todos las personas mayores de 6 meses de edad necesitan vacunarse contra la influenza (la gripe) todos los años. (Pregúntenos por la vacuna hoy mismo! Everyone 6 months of age and older without a contraindication

When to give a flu shot? It's time!

- Adults
 - Immunize by the end of October.
- Children 6 months 8 years old
 - If child never received vaccine before, then 2 doses ≥4 weeks apart.
 - First dose as soon as possible to complete 2-dose series by the end of October.
- Consider coadministration of flu and COVID-19 vaccines.
- Vaccination should continue throughout the season, as long as influenza viruses are circulating and unexpired vaccine is available.





Don't Wait. Vaccinate!

www.immunizeca.org/DontWaitVaccinate/



2021-22 INFLUENZA VACCINATION TALKING POINTS

FOR DRAFTING SOCIAL MEDIA MESSAGES, PRESS RELEASES, ARTICLES AND OTHER COMMUNICATIONS:

Getting flu vaccine is an easy step to protect yourself, your loved ones, and your community.

- Just like getting a COVID-19 vaccine, getting a flu shot is an easy way to help you and your family stay healthy.
- It is likely that both COVID-19 and flu will circulate this fall and winter.
- Even if you have already gotten a COVID-19 vaccine, you are still recommended to get a flu vaccine.
- Many people at higher risk for serious flu illness are also at higher risk for serious illness due to COVID-19. Getting immunized
 against flu and COVID-19 could save your life and protect your loved ones!
- If you haven't gotten vaccinated against COVID-19 yet, you can now receive COVID-19 and flu shots at the same time! It's safe and
 convenient.
- Flu vaccination will help lower the burden on the health care system by decreasing flu illnesses, hospitalizations, and deaths.
- Influenza and COVID-19 share many symptoms (e.g., fever, cough, fatigue, difficulty breathing, headaches, muscle pain, etc.).
 Preventing influenza means fewer people will need to seek medical care and testing for possible COVID-19 or influenza.
- CDC estimates that flu causes hundreds of thousands of hospitalizations and 12,000-61,000 deaths each flu season. While it's always
 important to prevent flu, it's especially important this season. A bad flu season combined with COVID-19 can put vulnerable
 populations at higher risk for illness.
- Depending on your age and health conditions, you can talk to your doctor about flu shot options that may be right for you. You can
 receive any flu vaccine product that you are eligible for.
- Flu vaccination is important for health care workers and others who live with or take care of vulnerable people to prevent spreading flu to them.

Resources

- CDC Clinician Outreach and Communication Activity (COCA): 2021-2022 Influenza Vaccination
 Recommendations and Guidance on Coadministration with COVID-19 Vaccines
 - https://emergency.cdc.gov/coca/calls/2021/callinfo_090921.asp
- CDC Frequently Asked Influenza (Flu) Questions: 2021-2022 Season
 - www.cdc.gov/flu/season/faq-flu-season-2021-2022.htm
- CDC Immunogenicity, Efficacy, and Effectiveness of Influenza Vaccines
 - www.cdc.gov/flu/professionals/acip/background/immunogenicity.htm
- California Department of Public Health (CDPH) Flu Resources
 - https://eziz.org/resources/flu-promo-materials/



Influenza Vaccination and HIV update

Philip Peters, MD
Office of AIDS Medical Officer

September 29, 2021 California Ryan White Webinar



Overview: Influenza Vaccination and HIV Update

1. Who should get a flu shot?

- Importance of the flu vaccinations for all people with HIV
- Considerations for people with HIV and other risk for severe illness

2. Review of Influenza Vaccine Types

- Formulations available for the 2021-22 Flu season
- Selecting the optimal vaccine for people with HIV

3. Flu and COVID-19 Vaccine considerations

- Best practices for coadministration of influenza and COVID-19 vaccines
- Assess COVID-19 vaccine status and need for an additional dose
- Health Equity vaccination disparities are known can Ryan White services anticipate and provide services to improve equity

A Flu Shot is the Best Protection Against Flu

- Core recommendation: Annual influenza vaccination is recommended for all people with HIV aged 6 months and older who do not have contraindications
- People living with HIV are a priority population for influenza immunization because they are at increased risk for severe influenza.

Grohskopf LA, Alyanak E, Ferdinands JM, et al. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices, United States, 2021–22 Influenza Season. MMWR Recomm Rep 2021;70(No. RR-5):1–28. DOI: http://dx.doi.org/10.15585/mmwr.rr7005a1.



High risk of serious influenza illness

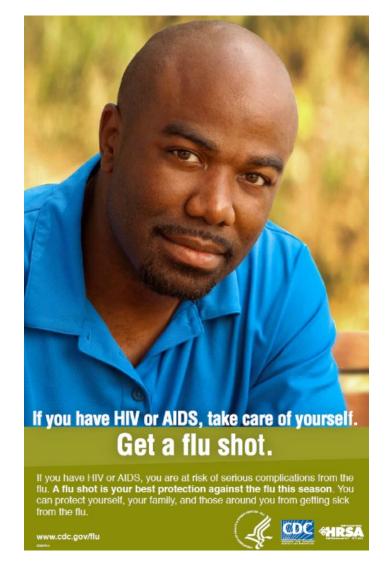
- People with HIV have a higher risk of developing serious flu-related complications
 - Increased risk for heart- and lung-related hospitalizations in people with HIV during flu season
 - Some people at risk for prolonged flu virus shedding
- Many people with HIV have conditions that increase their risk:
 - Older age over half of people with HIV in California are over 50 years of age
 - Chronic medical problems cardiovascular disease, chronic lung disease, kidney disease, and diabetes are more common in people living with HIV
 - Immune suppression indicated by a low CD4 T-cell count or not receiving antiretroviral treatment

Grohskopf LA, Alyanak E, Ferdinands JM, et al. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices, United States, 2021–22 Influenza Season. MMWR Recomm Rep 2021;70(No. RR-5):1–28. DOI: http://dx.doi.org/10.15585/mmwr.rr7005a1.

Influenza Vaccines are Effective in People with HIV

- Randomized studies in adults with HIV have shown that flu vaccination can reduce the risk of flu illness
 - In one study inactivated influenza vaccine was 75%
 effective at preventing confirmed influenza illness*

- Flu vaccination works much better for people living with HIV who are receiving ART
 - Seroconversion after vaccination for H1N1 was 71% among people on antiretroviral therapy (ART) vs. 35% among people not receiving ART*



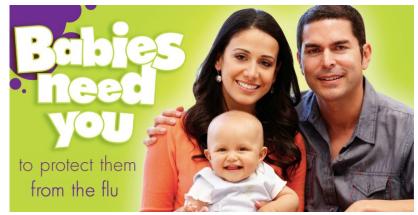
^{*} Ref: Madhi SA, et al. Clin Infect Dis. 2011 Jan 01;52(1):128-37 Summary of Immunogenicity, Efficacy, and Effectiveness of Influenza Vaccines: https://www.cdc.gov/flu/professionals/acip/background/immunogenicity.htm

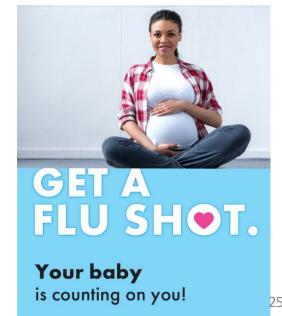
High Priority Groups

- Children 6 59 months
- Children & adolescents 6 mo. 18 yr. taking aspirin
- or salicylates

- Adults \geq 50 years
- Pregnant women
- All ages with chronic medical conditions
 - Immunocompromised
 - Respiratory: asthma, COPD
 - Metabolic: diabetes, obesity
 - Cardiovascular, renal, hepatic, neurologic, hematologic
 - Obesity (extreme, BMI ≥ 40 for adults)
- Nursing home residents
- American Indians/Alaska Natives

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High priority caregivers and contacts to people at risk

- Health care personnel
 - All people working in health-care settings who have potential for exposure to patients or to infectious materials
 - Not only people directly involved in patient care
- Household contacts and caregivers of children aged
 years and of adults aged ≥50 years
- Household contacts and caregivers of people with medical conditions associated with increased risk of severe complications from influenza



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High-Priority Persons for Influenza Vaccines during COVID-19

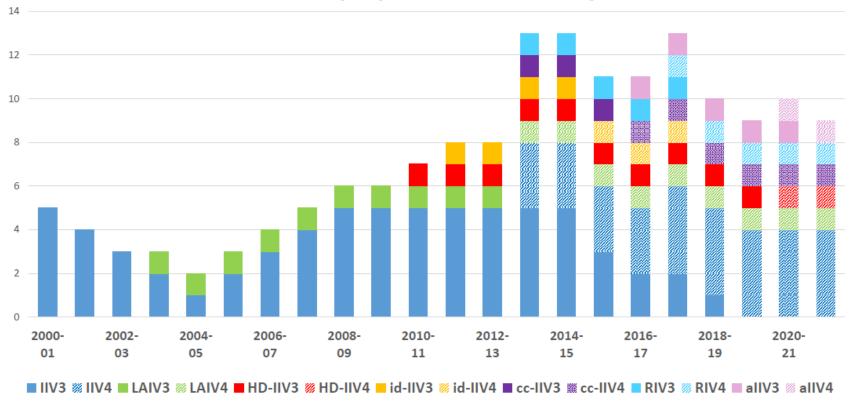
- Essential workers
- Persons at higher risk for severe illness from COVID-19
 - adults > 65 years
 - residents in nursing homes
 - people with chronic medical conditions
 - racial/ethnic groups disproportionately impacted by COVID-19
- Persons at higher risk for influenza complications
 - infants and young children; children with neurologic conditions
 - pregnant women
 - adults <u>></u> 65 years
 - people with chronic medical conditions



Which Influenza Vaccine Should I Receive?

U.S. Seasonal Influenza Vaccines Since 2000-2001

Number of unique products available by season



Abbreviations: **IIV** = Inactivated Influenza Vaccine; **RIV** = Recombinant Influenza Vaccine; **LAIV** = Live Attenuated Influenza Vaccine CDC. Clinician Outreach and Communication Activity (COCA). 2021-2022 Influenza Vaccination Recommendations and Guidance on Coadministration with COVID-19 Vaccines. Available at: https://emergency.cdc.gov/coca/calls/2021/callinfo_090921.asp. 28 Accessed: 9/17/21.

Influenza Vaccines Expected to be Available by Age Indication, United States, 2021-22 Influenza Season

Vaccine type		0 through 6 months	6 through 23 months	2 through 17 years	18 through 49 years	50 through 64 years	≥65 years
IIV4s	Standard-dose, unadjuvanted inactivated (IIV4)		Afluria Quadrivalent Fluarix Quadrivalent FluLaval Quadrivalent Fluzone Quadrivalent				
	Cell culture-based inactivated (ccllV4)		Flucelvax Quadrivalent				
	Adjuvanted inactivated (allV4)						Fluad Quadrivalent
	High-dose inactivated (HD-IIV4)						Fluzone High-Dose Quadrivalent
RIV4	Recombinant (RIV4)			Flublok Quadrivalent			
LAIV4	Live attenuated (LAIV4)			FluMist Qu	ıadrivalent		

IIV4=quadrivalent inactivated influenza vaccine RIV4=quadrivalent recombinant influenza vaccine LAIV4=quadrivalent live attenuated influenza vaccine Not approved for age group

| Egg-based | Not egg-based |

All vaccines expected for 2021-22 are quadrivalent (i.e., contain hemagglutinin derived from four viruses: one influenza A(H1N1), one influenza A(H3N2), one influenza B/Victoria and one influenza B/Yamagata.

Abbreviations: IIV = Inactivated Influenza Vaccine; RIV = Recombinant Influenza Vaccine; LAIV = Live Attenuated Influenza Vaccine

CDC. Clinician Outreach and Communication Activity (COCA). 2021-2022 Influenza Vaccination Recommendations and Guidance on Coadministration with COVID-19 Vaccines. Available at: https://emergency.cdc.gov/coca/calls/2021/callinfo_090921.asp. 29 Accessed: 9/17/21

Inactivated Influenza Vaccines (IIVs)

- Standard-dose, nonadjuvanted IIVs
 - Egg-based: hemagglutinin (HA) derived from reference vaccine viruses propagated in eggs
 - Four licensed products
 - Licensed for persons aged ≥6 months
- Quadrivalent:
 - influenza A (H1N1)pdm09
 - influenza A (H3N2)
 - influenza B (Victoria lineage)
 - influenza B (Yamagata lineage)
- One IIV4, Afluria Quadrivalent, is licensed for IM injection via the PharmaJet Stratis jet injector for persons aged 18 through 64 years

Stratis jet injector for persons aged 18 through 64 years

Grohskopf LA, Alyanak E, Ferdinands JM, et al. Prevention and Control of Seasonal Influenza with Vaccines:
Recommendations of the Advisory Committee on Immunization Practices, United States, 2021–22 Influenza Season. MMWR Recomm Rep 2021;70(No. RR-5):1–28. DOI: http://dx.doi.org/10.15585/mmwr.rr7005a1.



Recombinant and Cell-based Influenza Vaccines

- Recombinant influenza vaccine (RIV4)
 - HA produced in an insect cell line; manufactured without influenza viruses or eggs
 - Randomized controlled trial among 8,604 people aged at least 50 years: probability of influenza-like illness was 30% lower with RIV4 vs. IIV4
- Cell culture—based inactivated influenza vaccine (ccIIV4)
 - hemagglutinin (HA) derived from reference vaccine viruses propagated in canine kidney cells instead of eggs
- Persons with a History of Egg Allergy
 - Mild (only urticaria) = any licensed vaccine can be used
 - Severe egg allergy or severe allergic response to IIV = RIV4 and ccIIV4 are options
 - Vaccines can cause rare severe allergic reactions that are unrelated to egg allergy

Grohskopf LA, Alyanak E, Ferdinands JM, et al. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices, United States, 2021–22 Influenza Season. MMWR Recomm Rep 2021;70(No. RR-5):1–28. DOI: http://dx.doi.org/10.15585/mmwr.rr7005a1.

High-dose and Adjuvanted Influenza Vaccines

- Fluzone High-Dose Quadrivalent (HD-IIV4)
 - Licensed for persons aged ≥65 years, quadrivalent, inactivated, and egg-based
 - Contains four times as much antigen as standard-dose vaccines.
 - Randomized trial conducted over two influenza seasons among 31,989 people aged ≥65 years found that Fluzone High-Dose was 24% more effective than standard-dose vaccines
- Fluad Quadrivalent (allV4)
 - Licensed for persons aged ≥65 years, inactivated, and egg-based
 - Adjuvant: a substance added to a vaccine to increase the immune response.
 - MF59 adjuvant in Fluad is based on squalene, a naturally occurring oil
 - Small, observational study among older adults (65 years and older), Fluad was about 63% more effective than unadjuvanted inactivated influenza vaccine.

Precautions and Contraindications

- Guillain–Barré syndrome
 - Within 6 weeks following a previous dose of influenza vaccine
 - Precaution against further influenza vaccination
 - Option for influenza antiviral chemoprophylaxis
- Moderate or severe acute illness with or without fever
- History of Egg Allergy
- History of severe allergic reaction to an influenza vaccine (IIV)
 - Estimated 1.35 cases per million doses of influenza vaccine¹
 - If influenza vaccination is attempted with ccIIV4 or RIV (non-egg based options) medical monitoring to recognize and manage severe allergic reactions
 - Consider consulting an allergist to determine the responsible vaccine component

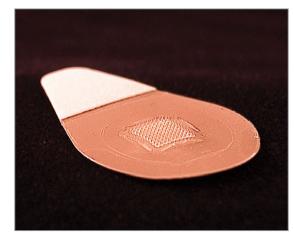
Live Attenuated Influenza Vaccine (LAIV4)

- Contraindicated in people with HIV (AIII graded recommendation)
 - Uncertain but biologically plausible risk associated with live virus
 - Limited data on efficacy in people with HIV
- Quadrivalent
- Standard-dose, nonadjuvanted IIVs
- Licensed for persons aged aged 2 through 49 years
- Egg-based

Grohskopf LA, Alyanak E, Ferdinands JM, et al. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices, United States, 2021–22 Influenza Season. MMWR Recomm Rep 2021;70(No. RR-5):1–28. DOI: http://dx.doi.org/10.15585/mmwr.rr7005a1. Wei, CJ., Crank, M.C., Shiver, J. *et al.* Next-generation influenza vaccines: opportunities and challenges. *Nat Rev Drug Discov* **19**, 239–252 (2020). https://doi.org/10.1038/s41573-019-0056-x

Next Generation Influenza Vaccines

- Additional non-egg-based vaccine options
 - vaccine viruses adapted for growth in eggs can develop mutations and become less effective
- Alternative vaccine methods to rapidly develop a vaccine for an emerging influenza virus – e.g., COVID-19 mRNA vaccine development
- Broadly protective vaccines that provide more effective and longer lasting immunities – universal vaccine
- Alternative, delivery methods to improve vaccine uptake – dissolving microneedle patch



Influenza and COVID-19 Vaccine Co-Administration

- Influenza and COVID-19 vaccines (or other vaccines) may be co-administered without regard to timing
 - Experience with non-COVID-19 vaccines indicates immunogenicity and adverse events are similar when vaccines are administered simultaneously
- Timing and Spacing
 - Separate injection sites by 1 inch or more
 - Some influenza vaccines (HD-IIV and aIIV) should be administered in a separate limb from Covid-19 vaccines if feasible (more local reaction)
 - Deltoid is the preferred site (anterolateral thigh alternative)

HIV-Specific Influenza Questions

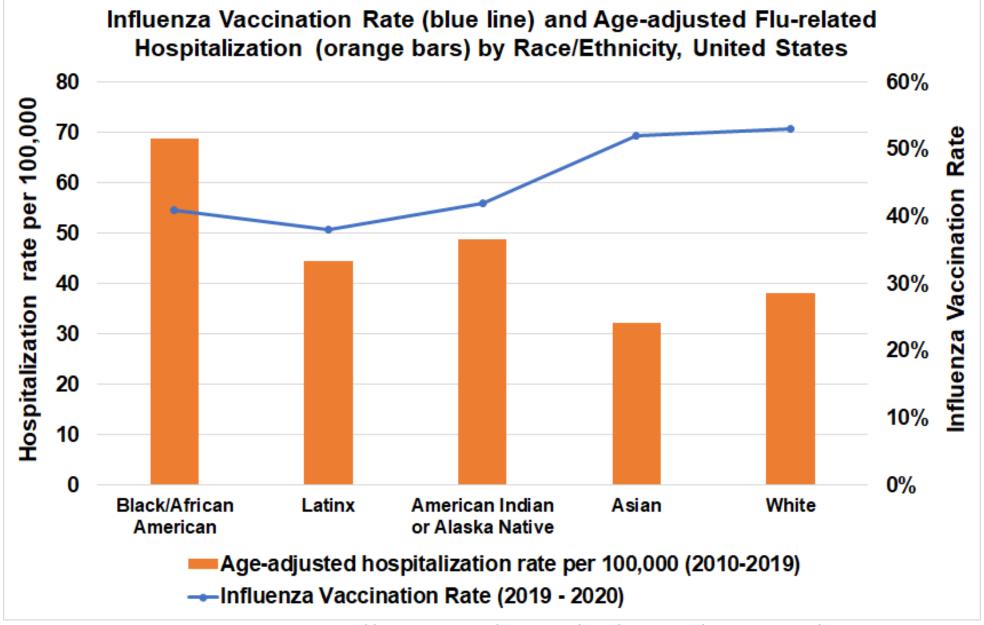
- Should older adults with HIV preferentially receive the high-dose (Fluzone High-Dose) or adjuvanted (Fluad) influenza vaccine?
 - Older adults living with HIV can receive these vaccines. Use of high-dose inactivated influenza vaccine is associated with decreased incidence of influenza and greater antibody response in adults without HIV aged ≥65 years. The ACIP and the CDC do not recommend these vaccine as preferred for use in older adults over the standard-dose, inactivated influenza vaccine. Vaccination should also not be delayed if a specific product is not readily available
- Are high-dose (Fluzone High-Dose) and adjuvanted vaccine (Fluad) recommended for people with HIV younger than 65 years of age?
 - No. Fluzone High-Dose and Fluad are licensed only for people age 65 years and older and are not recommended for younger people. One study found greater immunogenicity in individuals with HIV aged ≥18 years who were given high-dose influenza vaccine compared with standard-dose inactivated vaccine.
- What if I cannot receive an influenza vaccine and I have a high-risk exposure to influenza?
 - Postexposure antiviral chemoprophylaxis is an option within 48 hours of the exposure
 - Oseltamivir (or inhaled Zanamivir) for 7 days

COVID-19 Vaccine Questions (1)

- What is the difference between a booster vs additional dose?
 - The **additional dose** (third dose) of the COVID-19 mRNA vaccine is recommended for immunocompromised people to help build an initial adequate level of immunity. The "**booster dose**" are under consideration for people who developed initial immunity but enough time has past that their immunity might be starting to wane.
- Should I get a serology test to determine if I have protective immunity?
 - Not unless part of a research protocol, commercially available serology assays for SARS-CoV-2 are not recommended for assessing protective immunity in natural infections or after vaccination. COVID-19 vaccine studies have used specialized binding and neutralization antibody tests to inform research results. These specialized tests are not the same as commercial serology assays.

COVID-19 Vaccine Questions (2)

- What if my patient missed their second COVID-19 mRNA vaccine?
 - Provide the second COVID-19 mRNA vaccine dose as soon as possible, there is no need to restart the series. There is limited data on the effectiveness of mRNA COVID-19 vaccines administered beyond a six week (42 days) dosing interval but it is recommended to complete the series.
- What if my patient received a non FDA-authorized COVID-19 vaccine outside of the United States?
 - If the vaccine is listed for emergency use by the World Health Organization (WHO) and received all recommended doses, vaccination is considered complete. If vaccine is not listed for emergency use by WHO or they did not receive a full vaccine series, they should be offered a complete FDA-authorized COVID-19 vaccine series.



ACIP Influenza Vaccine Recommendations: https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/flu.html
ACIP General Best Practice Guidelines for Immunization: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html

Ryan White Services and Vaccine Health Equity

- Influenza and COVID-19 vaccine disparities exist by race and ethnicity
- When planning vaccination campaigns Access, Acceptance, Confidence
- Ryan White services to anticipate and provide services to improve equity
 - Outreach to people not vaccinated
 - Transportation assistance or home vaccination options
 - Technological assistance for scheduling appointments https://myturn.ca.gov/



Recap

- Who Should Get a Flu Shot?
 - All people with HIV, all health care personnel, all household contacts
- Which Influenza Vaccine is Preferred?
 - Any except live attenuated (don't delay)
 - High-dose and adjuvanted vaccines are options for older adults
- Co-administer Flu & COVID-19 Vaccines
- Plan to reduce vaccine inequities





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- Anna Flynn

Flu Vaccine: Covered by AIDS Drug Assistance Program (ADAP)





ADAP's Medication Assistance Program

- >ADAP's mission
- ➤ ADAP formulary
- California ADAP Formulary is available at https://cdph.magellanrx.com/provider/docume nts
 - Alphabetical by Generic
 - Formulary by Class





ADAP Client Eligibility Requirements

- 1. 18 years of age or older
- 2. HIV/AIDS diagnosis
- 3. California resident
- 4. Modified Adjusted Gross Income (MAGI) at or below 500% of Federal Poverty Level (FPL) based on family size and household income.
- 5. Not fully covered by Medi-Cal or any other payer source (third-party payer)



ADAP Coverage by Client Type:

- ➤ ADAP covers the flu vaccine and the administration fee
- ➤ How to get vaccinated?

ADAP Uninsured Clients

Uninsured ADAP clients must visit a pharmacy that provides the flu vaccination and is in ADAP's pharmacy network.

The flu vaccine, which includes the administration fee, will be covered by ADAP.

ADAP Insured Clients

Insured ADAP clients have to follow their health insurance provider's guidelines and processes to get vaccinated.



How to get vaccinated?



ADAP Uninsured Clients

- Contact a local ADAP pharmacy
- Confirm that they give flu shots
- Schedule an appointment, if required
- Take the ADAP Pharmacy Benefits Card to the pharmacy.

*ADAP clients will not have any outof-pocket costs. ADAP pays for the flu vaccine and the administration fee.



ADAP Insured Clients

Follow the health insurance provider's guidelines and processes to get vaccinated.

*ADAP clients will not have any out-of-pocket expenses associated with receiving a flu vaccine.



Contact Us

CALL CENTER HOURS:

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