Centers for Disease Control and Prevention National Center for Immunization and Respiratory Diseases



Vaccination Planning for the 2020-2021 Influenza Season

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2019-2020 Influenza Activity

Influenza Positive Tests Reported to CDC by U.S. Public Health Laboratories, 2019-20 Season



Summary of 2019-2020 influenza season

Two consecutive waves

- 1st wave predominantly influenza B/Victoria viruses
- 2nd wave driven by influenza
 A (H1N1)
- Pediatric deaths reported to CDC for the 2019-2020 season: 185*



*As of June 13, 2020

https://www.cdc.gov/flu/about/burden/preliminary-in-season-estimates.htm

Percentage of Visits for Influenza-like Illness (ILI) Reported by the U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet), Weekly National Summary, 2019-2020 and Selected Previous Seasons



Cumulative Rate of Laboratory Confirmed Influenza-Associated Hospitalizations, FluSurvNet, 2009-10 - 2019-20



Influenza-Associated Mortality





MMWR Week

WG Considerations and Proposed 2020-21 Recommendations

2020-21 Core Recommendation (Unchanged)

Annual influenza vaccination is recommended for all persons aged 6 months and older who do not have contraindications.

2020-21 Primary Updates

- U.S. influenza vaccine viral composition
- Inclusion of two recently licensed vaccines
 - -Fluzone High-Dose Quadrivalent
 - -Fluad Quadrivalent

2020-21 Influenza Vaccine Composition

- *Egg based* influenza vaccines will contain hemagglutinin derived from:
 - an A/Guangdong-Maonan/SWL1536/2019 (H1N1)pdm09-like virus;
 - -an A/Hong Kong/2671/2019 (H3N2)-like virus;
 - -a B/Washington/02/2019 (Victoria lineage)-like virus; and
 - (for quadrivalent vaccines) a B/Phuket/3073/2013 (Yamagata lineage)-like virus.
- Non-egg based influenza vaccines will contain hemagglutinin derived from:
 - an A/Hawaii/70/2019 (H1N1)pdm09-like virus;
 - -an A/Hong Kong/45/2019 (H3N2)-like virus;
 - a B/Washington/02/2019 (Victoria lineage)-like virus; and
 - a B/Phuket/3073/2013 (Yamagata lineage)-like virus.

Recent Influenza Vaccine Licensures

- November 2019: Fluzone High-Dose Quadrivalent (Sanofi Pasteur) licensed for ≥65 years
 - -60 mcg hemagglutinin per vaccine virus in a 0.7 mL dose (240mcg total)
 - -Will replace previous trivalent Fluzone High-Dose for 2020-21
 - Pre-licensure data presented to the ACIP in October, 2019
- February 2020: Fluad Quadrivalent (Seqirus) licensed for ≥65 years
 - Contains MF59 adjuvant, similarly to the previously licensed trivalent formulation of Fluad
 - Pre-licensure data presented to the ACIP in February, 2020

Changes to the

Contraindications and Precautions Table (Table 2)

- Contraindications/precautions table:
 - "Contraindications and conditions for which use is not recommended" header changed to "Contraindications"
 - Text provides more detail concerning which contraindications are labeled contraindications in the package insert, and which are ACIP Recommendations.

Vaccine Adverse Event Reporting System (VAERS): Review of Live Attenuated Influenza Vaccine (LAIV) in Special Populations

- Conducted targeted review in VAERS for LAIV reports in 2 special populations of interest
 - Asplenia or sickle cell disease
 - Cerebrospinal fluid leak or cochlear implant
- VAERS *
 - United States spontaneous reporting surveillance system
 - Operating since 1990
 - Co-managed by CDC and FDA
 - Receives adverse event reports from manufacturers, medical providers, vaccine recipients and the general public

VAERS Reports after LAIV in Special Populations: Methods

- Primary U.S. reports
- Time period: July 1990 March 16, 2020
- Vaccines: LAIV (monovalent, trivalent or quadrivalent) with or without other vaccines
- Age: no restriction
- Search criteria: two different search methods used
 - Medical Dictionary for Regulatory Activities (MedDRA) preferred terms
 - Text string search
- Serious report definition: death, life-threatening illness, hospitalization or prolongation of hospitalization, permanent disability, congenital anomaly or birth defect (based on the Code of Federal Regulations)

VAERS Reports after LAIV in Special Populations: Results

- Asplenia or sickle cell disease: 2 reports
 - Sickle cell anemia: 1 child, non-serious report
 - Asplenia/splenectomy: 1 adult, death report*
- CSF Leak or cochlear implant: 3 reports
 - CSF Leak: 0 reports
 - Cochlear implant: 3 children, non-serious reports

* Person had history of splenectomy; cause of death reported as *Streptococcus pneumoniae* sepsis

LAIV4 use in Settings of Asplenia, Cochlear Implant, and Active CSF Leaks

- Literature search
 - Terms based on "influenza vaccine" and "Cochlear implant", "cerebrospinal fluid leak", "CSF leak", "anatomic asplenia", "functional asplenia", or "sickle-cell anemia"
 - -141 citations
 - No data related to use of LAIV in these populations

LAIV4 use in Settings of Asplenia, Cochlear Implant, and Active CSF Leaks

- Work Group Discussion:
 - Insufficient data for use in these populations
 - Alternative vaccines are available
 - In the proposed document, these conditions have been added to list of contraindications for LAIV4 (previously only discussed in text)

Influenza Antivirals and LAIV4

- Previously indicated that use of antivirals from 48 hours before to 2 weeks after administration of LAIV4 may interfere with vaccine
- Newer antivirals peramivir and baloxavir have longer half-lives than oseltamivir and zanamivir
- Insufficient data available on use of LAIVs in setting of antiviral use
- Based on half-lives, language added indicating prudent to assume interference possible if antivirals are administered within these intervals:

Antiviral	Interval
Oseltamivir and Zanamivir	48 hours before to 2 weeks after LAIV4
Peramivir	5 days before to 2 weeks after LAIV4
Baloxavir	17 days before to 2 weeks after LAIV4

Vaccination of Persons with Egg Allergy

- Language concerning persons with a history of severe allergic reaction to egg (having had any symptom other than hives after egg ingestion) updated to reflect availability of two egg-free vaccines, the cell-culture based inactivated vaccine (cclIV4) and the recombinant influenza vaccine (RIV4).
- For these individuals, if a vaccine other than ccllV4 or RIV4 is used, the selected vaccine should be administered in an inpatient or outpatient medical setting, supervised by a health care provider who is able to recognize and manage severe allergic reactions.

Summary of Changes

- Principal changes:
 - 2020-21 U.S. Influenza vaccine composition
 - Inclusion of Fluzone High-Dose Quadrivalent and Fluad Quadrivalent
- Other changes:
 - Table 2 now says "Contraindications" rather than "Contraindications and conditions for which use is not recommended"
 - Asplenia, cochlear implant, and active CSF leak included in contraindications in Table 2
 - Updated guidance concerning LAIV4 and influenza antivirals based on halflives of the various agents
 - Updating of language concerning vaccination of persons with egg allergy to reflect availability of egg-free vaccines

Ensure patients receive routine vaccines

COVID-19 pandemic and disruptions to routine childhood vaccination

Weekly decreases in Vaccines for Children program provider orders for pediatric vaccines – United States, January 6-June 1, 2020



All non-influenza vaccines

Notable Dates:



2) 3/13/2020: US national emergency declared

Routine immunization services remain critical

- Routine vaccination helps protect individuals from serious diseases and prevents illnesses that lead to increased medical visits and hospitalizations further straining the healthcare system.
- Influenza vaccination will be critical to reduce the impact of respiratory illnesses and resulting burdens on the healthcare system during the COVID-19 pandemic.

Decreasing immunization rates means it is particularly important to:

- Assess the vaccination status of all patients to avoid missed opportunities and ensure timely vaccination catch-up.
- Administer all vaccines due or overdue according to the recommended <u>CDC</u> <u>immunization schedules</u> during each visit.





Vaccine	19-26 years	27-49 years	50-64 years	265 years	
Influenza inactivated (IV) or Influenza recombinant (IV)		1 dose annually			
Influenza live, attenuated (LAIV)		1 doce annually			
Tetanus, diphtheria, pertussis (Tdap or Td)	1 dose Tdap, then Td or Tdap booster every 10 years				
Measles, mumps, rubella (MMR)	3 or 2 doses depending on indication ()d born in 1952 or later)				
Varicella (VAR)	2 doses (If born in 1980 or later)		2 dese	2 doses	
Zoster recombinant (R2V) preferred			24	ites	
Zoster live (ZVL)			14		
Human papillomavieus (HPV)	2 or 3 doses depending on age at initial vaccination or condition	27 through 45 years			

https://www.cdc.gov/vaccines/pandemic-guidance/index.html

Considerations for routine vaccination

- Children and adolescents: Reschedule missed well-child visits and/or recommended vaccinations; prioritize newborns, infants, and children up to 24 months, young children, then extend through older children and adolescence.
- Pregnant women: If vaccination has been delayed, administer vaccines during the next in-person appointment.
- Adults: Continue to ensure patients are receiving recommended vaccines, especially older adults and those with underlying medical conditions.

https://www.cdc.gov/vaccines/pandemic-guidance/index.html

Increasing Seasonal Influenza Vaccine Coverage to Decrease Healthcare Utilization, 2020-21

- Expect SARS-CoV-2 to continue to circulate in the fall
- Increasing flu vaccination coverage will reduce stress on the healthcare system
 - Decrease doctor visits and hospitalizations
 - Reduce use of diagnostics
- Focus on adults at higher risk from COVID-19
 - staff and residents of LTCF
 - -adults with underlying illnesses
 - -African-Americans, Hispanics, American Indians and Alaska Natives
 - adults who are part of critical infrastructure

Influenza vaccination

Use every opportunity to administer influenza vaccines to all eligible persons, including:

- Essential workers: Healthcare personnel and other critical infrastructure workforce
- Persons at increased risk for <u>severe illness from COVID-19</u>, including older adults and those with underlying medical conditions
- Severe illness from COVID-19 has been shown to disproportionately affect members of certain <u>racial/ethnic minority groups</u>.
- Persons at <u>high risk for influenza complications</u>

Catch-up vaccination strategies



Forecasting through EHR or IIS*



Standing orders



*Electronic health record (EHR) or immunization information system (IIS)

U.S. Community Preventive Services Task Force. Guide to Community Preventive Services. Vaccination Programs. https://www.thecommunityguide.org; Photo credit: Noun project

Vaccination documentation

Because patients may be receiving vaccines outside their medical home, it is critical all vaccinations are documented in an Immunization nformation system (IIS) or electroni record (EHR) for accurate and timely information on patient vaccination status.



How to safely administer vaccines during the COVID-19 pandemic

Persons with suspected or confirmed COVID-19

 Routine vaccination should be deferred for persons with suspected or confirmed COVID-19, regardless of symptoms.



https://www.cdc.gov/vaccines/pandemic-guidance/index.html

Implement enhanced infection control measures

- Screen patients for COVID-19 symptoms before and during the visit.
- Maintain physical distancing (at least 6 feet apart, where possible)
- Limit and monitor facility points of entry and install barriers to limit physical contact with patients at triage.
- Practice respiratory hygiene (facemasks for staff and cloth face coverings for patients over 2 years of age, if tolerated) and cough etiquette
- Practice hand hygiene (including at least 60% alcohol hand sanitizer for patients)
- Enhance surface decontamination

Refer to guidance to prevent the spread of COVID-19 in <u>healthcare settings</u>, including outpatient and ambulatory care settings.

Use personal protection equipment

Face mask



 Recommended: All healthcare providers (N95 masks not recommended)

Eye protection



- Recommended: Areas of moderate/substantial community transmission
- Optional: Areas of minimal/no community transmission

Gloves



- Recommended: Intranasal or oral vaccines
- Optional: Intramuscular or subcutaneous vaccines

Ensure physical distancing during vaccination visits

Separate sick from well patients



- Schedule well and sick visits at
 different times of the day.
- Place sick patients in different areas of the facility or different locations.

Ensure physical distancing measures



- At least 6 feet during all aspects of visit: check-in, checkout, screening procedures, postvaccination monitoring
- Use strategies such as physical barriers, signs, ropes, floor markings.

Reduce crowding in waiting room



Ask patients to wait outside (e.g., in their vehicles) until called in.

Reassure patients through communication

- Communicate the importance of vaccination to patients and parents/caregivers.
- Explain the safety protocols and procedures of your office.



https://www.cdc.gov/vaccines/pandemic-guidance/index.html

Information for alternative vaccination sites

Alternative vaccination sites

- Pharmacies
- Non-traditional facilities such as schools and churches
- Curbside clinics
- Drive-through clinics
- Mobile outreach units
- Home visits

Alternative vaccination site guidance during COVID-19

Follow clinical setting guidance and take additional precautions:

- Select a space large enough to ensure physical distancing.
- Provide specific appointment times and use other strategies to manage patient flow and avoid crowding.
- Set up unidirectional site flow with signs, ropes, or other measures.
- Have a separate vaccination area or separate hours for persons at increased risk for severe illness from COVID-19.

https://www.cdc.gov/vaccines/pandemic-guidance/index.html



Updates and resources

Vaccination guidance is continuously being reviewed and updated

- Visit <u>https://www.cdc.gov/vaccines/pandemic-guidance/index.html</u> for the most recent guidance.
- Sign up to be notified when information on the web page changes.



COVID-19 operational guidance

- State and local health departments:
 - https://www.cdc.gov/coronavirus/2019-ncov/php/index.html
- Clinical care:
 - https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care.html
- Long-term care facilities:
 - https://www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html

Influenza vaccination planning for 2020-2021 season

- Maximize available vaccine supply
 - Expect >180M doses for U.S. market
- Operational considerations
 - Outreach to those at higher risk
 - Planning for potential need for social distancing
 - Extending influenza vaccination season (September through December or later)
- Enhancing communication
 - Align with COVID-19 messaging
 - Messaging for African-American and Hispanic communities

Influenza Vaccine Doses Distributed By Season, 2008-9 to 2019-20, and Projected, 2020-21



Doses (millions)

Sources of 2019–20 Influenza Season Data

- Updated surveillance information is available each Friday
 - –FluView, static report: https://www.cdc.gov/flu/weekly/
 - –FluView Interactive, online application: https://www.cdc.gov/flu/weekly/fluviewinteractive.htm
- Vaccine effectiveness estimates
 - –Morbidity and Mortality Week Report (MMWR) updates: https://www.cdc.gov/mmwr/index.html
 - –Advisory Committee on Immunization Practices (ACIP) meetings: https://www.cdc.gov/vaccines/acip/meetings/index.html

Additional CDC Resources

- CDC Influenza homepage: <u>https://www.cdc.gov/flu/</u>
- Influenza surveillance: <u>https://www.cdc.gov/flu/weekly/fluactivitysurv.htm</u>
- Influenza vaccination coverage: <u>https://www.cdc.gov/flu/fluvaxview/index.htm</u>
- For Professionals: <u>https://www.cdc.gov/flu/professionals/index.htm</u>
 - Vaccination homepage:
 - https://www.cdc.gov/flu/professionals/vaccination/index.htm
 - 2017-18 ACIP Influenza Recommendations:

https://www.cdc.gov/mmwr/volumes/66/rr/rr6602a1.htm

– Antiviral homepage:

https://www.cdc.gov/flu/professionals/antivirals/index.htm

For Children (created by CDC and endorsed by the AAP): activity book <u>https://www.cdc.gov/phpr/readywrigley/documents/ready_wrigley_flu.pdf</u>

Thank you

For more information, contact CDC 1-800-CDC-INFO (232-4636) TTY: 1-888-232-6348 www.cdc.gov

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Additional Slides on Immunization Services

Substantial disruptions to outpatient medical care during COVID-19 pandemic

As number of COVID-19 cases increased and stay-at-home orders implemented, nearly 70% reduction in outpatient visits before starting to rebound



https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html; Ateev, M. et al., To the Point (blog), Commonwealth Fund, updated May 19, 2020.

Signs of recovery in routine childhood vaccination

Weekly Vaccines for Children program provider orders for pediatric vaccines – United States, January 6-June 1, 2020



Notable Dates:





CDC Antiviral Treatment Recommendations

- Antiviral treatment is recommended as early as possible for any patient with confirmed or suspected influenza who is:
 - -Hospitalized
 - -Has severe, complicated, or progressive illness
 - Is at high risk for influenza complications

People at High Risk for Influenza Complications for Whom Antiviral Treatment is Recommended

- Children <2 years old (although all children <5 years old are considered at high risk for complications, highest risk is for children <2 years old)
- Adults age 65 years and over
- Pregnant/postpartum women
- Children <18 years old receiving long-term aspirin therapy</p>
- American Indians/Alaska Natives
- People with underlying medical conditions (e.g., pulmonary, cardiac, immunosuppression, neurologic and neurodevelopment conditions)
- Residents of nursing homes/chronic care facilities

https://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm

People at High Risk for Influenza Complications for Whom Antiviral Treatment is Recommended

- Antiviral treatment is recommended as early as possible for any patient with confirmed or suspected influenza who is:
 - Hospitalized
 - Has severe, complicated, or progressive illness
 - Is at high risk for influenza complications
- Antiviral treatment can be considered for any previously healthy, symptomatic outpatient not at high risk with confirmed or suspected influenza on the basis of clinical judgment, if treatment can be initiated within 48 hours of illness onset
- Clinical benefit is greatest when antiviral treatment is administered early
- Three FDA-approved antivirals are recommended for use in the United States: oral oseltamivir, inhaled zanamivir, and intravenous peramivir

https://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm