1

Acronyms/Terminology

VRBPAC – Vaccines and Related Biologic Products Advisory Committee

ACIP – Advisory Committee on Immunization Practices

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Recent Meetings

ACIP Meeting
February 22-24, 2023

VRBPAC Meeting
February 28-March 1, 2023

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ACIP February 2023 Topics

- Mpox Vaccine
- Influenza Vaccine
- Pneumococcal Vaccines
- Meningococcal Vaccines
- Polio Vaccine
- RSV Vaccines – Pediatric/Maternal
- RSV Vaccines – Adult
- Chikungunya Vaccine
- Dengue Vaccines
- Varicella
- COVID-19 Vaccines

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ACIP – Mpox Vaccine

- >30,000 cases of mpox in the U.S. since May 2022
- Low numbers continuing
- Predominantly among men (gay, bisexual, and men who have sex with men)
- 2 vaccines available
  - Jynneos received an FDA EUA for pre- or post-exposure prophylaxis in children and intradermal administration in adults
  - ACAM2000 not being utilized in this outbreak
- Nearly 1.2 million doses of Jynneos administered during this outbreak
- Apparent equity issues

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ACIP – Mpox Vaccine

- No previous ACIP recommendation for Jynneos usage during outbreaks
- Efficacy data reviewed: 66%-83% after 2 doses regardless of route
- Safety data reviewed: no new concerns (myocarditis and pericarditis post-vaccination rates similar to general population)
- ACIP vote: recommend 2-dose Jynneos series (28 day separation) in people 18 and older at risk of mpox during an outbreak as defined by public health authorities
  - Subcutaneous administration recommended unless supply dictates intradermal administration
  - Utilization in individuals <18 years will be addressed at the June 2023 meeting
  - A more long-term strategy for Jynneos will be reviewed at the October 2023 meeting

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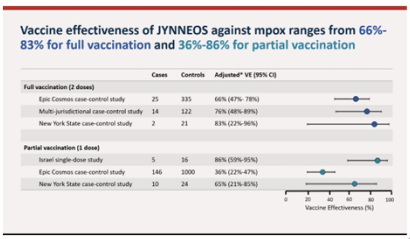
ACIP – Mpox Vaccine



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ACIP – Influenza Vaccine

- Early peak in U.S., late November/early December 2022
- Vast majority of cases have been Influenza A(H3N2) subtype
- Estimated 25 million illnesses, 280,000 hospitalizations, and 18,000 deaths
- Collected viruses susceptible to available antivirals

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ACIP – Influenza Vaccine

- Numerous studies of 2022-23 season vaccine efficacy, including NVSN, IVY, VISION Network, and Marshfield Clinic Research Institute
- Overall vaccine efficacy for 2022-23 season 49%
- Conveys significant protection in from hospitalization and in high-risk groups

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ACIP – Influenza Vaccine

Network – Population & Infection Severity	Efficacy
NVSN – Pediatric hospitalizations	68%
NVSN – Pediatric emergency department visits	42%
IVY – Adult hospitalizations	43%
VISION – Adult hospitalizations	39%
VISION – Adult emergency department/Urgent care visits	44%
Marshfield – Medically attended influenza A in children and working aged adults	54%
Marshfield – Symptomatic influenza A in children	71%

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ACIP – Pneumococcal Vaccines

Current recommendations:

- PCV13 – children
- PCV15 – children and adults
- PCV20 – adults and under FDA review for children with potential licensure as early as April 2023
- PPSV23 – some children based on their risks and adults with high-risk conditions

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ACIP – Pneumococcal Vaccines

CDC recommends pneumococcal vaccines for people at increased risk

Children

All children younger than 5 years old should receive PCV13 or PCV15.

Children 5 through 18 years old with certain medical conditions that increase their risk of pneumococcal disease should receive PCV13 or PCV15.

Children 2 through 18 years old with certain medical conditions should also receive PPSV23.

Adults

Adults who have never received a pneumococcal conjugate vaccine should receive PCV15 or PCV20 if they

- Are 65 years and older
- Are 19 through 64 years old and have certain medical conditions or other risk factors

If PCV15 is used, it should be followed by a dose of PPSV23.

Adults who received an earlier pneumococcal conjugate vaccine (PCV13 or PCV7) should talk with a vaccine provider to learn about available options to complete their pneumococcal vaccine series.

Adults 65 years or older have the option to get PCV20 if they have already received

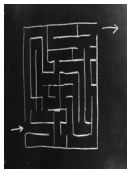
- PCV13 (but not PCV15 or PCV20) at any age

and

- PPSV23 at or after the age of 65 years old

These adults can talk with their doctor and decide, together, whether to get PCV20.

Some people may need more than one dose of pneumococcal vaccines. Talk with your or your child's doctor about what is best for your specific situation.



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ACIP – Pneumococcal Vaccines

PCV20

- No anticipated impact to adult recommendations
- Reviewed possible schedules for children under 2 years – 4 doses vs. 3 doses of PCV13
- Discussed possibility of recommending PCV20 in place of PPSV23 in older children with underlying health conditions
- 20 is more than 13 or 15, so…?
- ACIP vote on recommendations anticipated after product licensure, likely in June 2023

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ACIP – Meningococcal Vaccines

- Decreased cases during pandemic, but numbers doubled in 2022
- 27 cases since 2019 of penicillin and ciprofloxacin resistant serogroup Y
- Serogroup B dominant in adolescents
- Currently MenACWY and MenB approved

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ACIP – Meningococcal Vaccines

- Pfizer MenABCWY pentavalent vaccine Phase 3 trial
- 2 dose series 6-12 months apart with a booster dose 4 years later
- ACIP Work Group considered the pentavalent vaccine noninferior to MenACWY + MenB, but some information lacking
- ACIP will continue to review at the June 2023 meeting and likely vote on any recommendations at the October 2023 meeting

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ACIP – Polio Vaccine

- Discussion surrounding possibility of an updated recommendation for using IPV in adults
  - Primary series or booster dose
  - Immunocompromised adults
  - Unvaccinated/incompletely vaccinated adults
- No anticipated impact to child recommendations
- Further discussion and possible vote at June 2023 meeting

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ACIP – Pediatric/Maternal RSV Vaccines

- United States season typically November-March
- Infects 97% of children by age 2
- Leading cause of hospitalizations in infants in the U.S.
- Pre-exposure prophylaxis available, but only 2% of infants meet palizivumab (Synagis®) indications
- No vaccine currently available for RSV

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ACIP – Pediatric/Maternal RSV Vaccines

- Nirsevimab – monoclonal antibody in joint development from Sanofi and AstraZeneca
- Potential recommendations:
  - All children born during RSV season
  - Children <8 months old during RSV season
  - High risk children during second RSV season
- FDA has third quarter 2023 as target action date for their decision
- Unknown if it will be included in the Vaccines For Children Program

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ACIP – Pediatric/Maternal RSV Vaccines

- Nirsevimab – a monoclonal antibody in joint development from Sanofi and AstraZeneca
- For the prevention of RSV lower respiratory tract disease in newborns and infants entering or during their first RSV season and for children up to 24 months who remain vulnerable to severe RSV disease through their second RSV season
- 79% efficacy against medically attended LRTI due to RSV, 80.6% efficacy against hospitalization, and 90% efficacy against ICU admission
- FDA has third quarter 2023 as target action date for their decision
- Cost, access, and administrative questions

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ACIP – Pediatric/Maternal RSV Vaccines

- Pfizer bivalent RSV Prefusion (RSVpreF) vaccine product being studied for administration during pregnancy
- One dose at 24-36 weeks gestation to provide passive immunity to infants against LRTI and severe LRTI caused by RSV
- Phase 3 findings suggest a favorable safety profile and 82% efficacy against severe RSV up to 3 months of age and 69% at 6 months
- If licensed by the FDA, ACIP vote anticipated at October 2023 meeting

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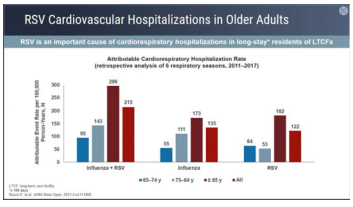
ACIP – Adult RSV Vaccines

- Each year in the U.S. leads to 177,000 hospitalizations and 14,000 deaths among adults 65 years and older.



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ACIP – Adult RSV Vaccines

- Pfizer (bivalent RSVpreF) and GSK (adjuvanted RSVpreF3) each have a RSV vaccine in development for older adults
- In trials, both have shown efficacy against lower respiratory tract infections
  - GSK: 82.5% efficacy against RSV Lower Respiratory Tract Disease and 87.5% against medically attended RSV Lower Respiratory Tract Disease
  - Pfizer: 85.7% efficacy against RSV Lower Respiratory Tract Illness and 80.00% against medically attended RSV Lower Respiratory Tract Illness
- Safety: concerns about adverse events with both products, particularly Guillain-barre syndrome
- Trials were conducted in adults 60 years and up, ACIP Work Group considering 65 years and up
- More data needed and products will be discussed at future meetings

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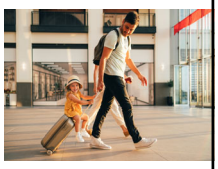
ACIP – Travel Vaccines – Chikungunya Virus

Chikungunya – virus spread via mosquito bite



- Symptoms can be prolonged
- Outbreaks occur in many places around the world
- Death rare
- Vaccine from Valneva may be licensed by FDA in August 2023
- ACIP vote likely at February 2024 meeting

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ACIP – Travel Vaccines – Dengue Virus

Dengue – virus spread via mosquito bite

- Symptoms can be prolonged symptoms
- Outbreaks occur in many places around the world
- About 1 in 20 people progress to severe dengue
- A vaccine is approved for children 9-16 years with laboratory-confirmed prior dengue infection who live in places where dengue is common
- New vaccine from Takeda being reviewed by FDA, possible long term protection for both naïve and previously infected individuals
- ACIP will continue review at the June 2023 meeting and vote at the October 2023 meeting

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ACIP – 25 years of Varicella Vaccine

Varicella vaccine over the last 25 years:

- Has prevented up to 91 million cases of chickenpox
- Has prevented 238,000 hospitalizations for chickenpox
- Has prevented up to 2,446 deaths
- Societal cost savings of more than $23 billion

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ACIP – COVID-19 Vaccines

Efficacy

- Continue to be highly effective with regards to serious outcomes
- Hospitalization rate in unvaccinated adults 16 times that of adults receiving a bivalent mRNA booster
- Hospitalization rate in vaccinated adults without a bivalent booster 2.6 times that of adults receiving a bivalent booster

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ACIP – COVID-19 Vaccines

Safety

- November 2022 possible safety signal for ischemic stroke in adults 65 years and up in Vaccine Safety Datalink (VSD)
  - No other vaccine surveillance system domestically or internationally reflected a similar safety signal and signal has since diminished
  - Further review showed signal was stronger when Pfizer bivalent booster and influenza vaccine given concurrently
  - No causal link proven, investigation continues
  - No change in vaccination recommendations
- Safety data for the bivalent booster do not show an increased risk of myocarditis in adolescent males

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ACIP – COVID-19 Vaccines

Simplification of recommendations under consideration

- Adopt a 1-dose schedule after early childhood
- End use of monovalent vaccines, utilizing bivalent for both primary series and booster
- NO changes at this time

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VRBPAC February-March 2023 Topics

- Safety and effectiveness of ABRYSVO, Pfizer's Respiratory Syncytial Virus Vaccine for adults 60 years and older
- Safety and effectiveness of AVEXVY, GSK's Respiratory Syncytial Virus Vaccine, Recombinant, Adjuvanted for adults 60 years and older

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VRBPAC February-March 2023

ABRYSVO Continued Monitoring

Pharmacovigilance Plan

FDA

The Applicant will conduct passive and active surveillance activities for continued vaccine safety monitoring, including routine pharmacovigilance.

Missing information	Immunocompromised older adults
Surveillance Activities	• Planned postmarketing safety study in immunocompromised older adults
Important Potential Risks	• GBS and other immune-mediated demyelinating conditions • Cardiac disorders
Surveillance Activities	• Expedited reporting for all cases of GBS and other immune-mediated demyelinating conditions and Cardiac disorders • Aggregate analysis of GBS and other immune-mediated demyelinating conditions and Cardiac disorders in periodic safety reports • Planned postmarketing safety study to assess the risk of GBS and other immune-mediated demyelinating conditions among individuals vaccinated with ABRYSVO (RSVpreF)

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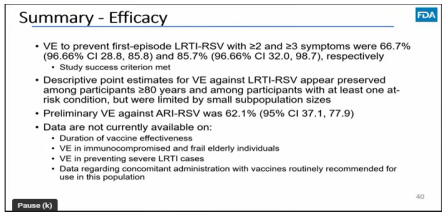
ABRYSVO
Efficacy



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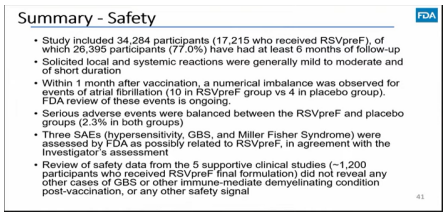
ABRYSVO
Safety



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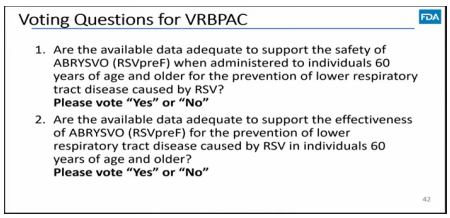
ABRYSVO
1. 7 yes
   4 no
   1 abstain
2. 7 yes
   4 no
   1 abstain



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VRBPAC February-March 2023

AVEXVY Continued Monitoring

Pharmacovigilance Plan

Missing information	Immunocompromised older adults
Surveillance Activities	• A post-authorization clinical trial evaluating AREXVY in immunocompromised individuals is being designed
Important potential risks	Potential Immune-Mediated Disorders (pIMDs)

Surveillance activities	Applicant will conduct passive surveillance activities for continued vaccine safety monitoring, including routine pharmacovigilance and:
	• Expedited reporting for all cases of:
	  • GBS, ADEM, and other immune-mediated demyelinating conditions and neurologic conditions
	  • Supraventricular arrhythmias
	• Aggregate analysis, in periodic safety reports, for:
	  • GBS, ADEM, and other immune-mediated demyelinating conditions
	  • Supraventricular arrhythmias

Note that the following are currently under discussion between FDA and the Applicant:
- Plans for a postmarketing safety study to assess the risk of GBS, ADEM, and other immune-mediated demyelinating conditions among individuals vaccinated with AREXVY.
- Determination of the inclusion of Cardiac Disorders as an *important potential risk* in the PVP.

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VRBPAC February-March 2023

AVEXVY Efficacy

Summary: Efficacy

- VE against first occurrence of RT-PCR-confirmed RSV LRTD was 82.6% (96.95% CI 57.9, 94.1) in adults ≥60 YOA
- Subgroup analysis showed that VE was demonstrated for: RSV-A and RSV-B virus subtypes; age groups 60-69 YOA and 70-79 YOA; participants with at least 1 pre-existing comorbidity of interest, and RSV-ARI.
  - VE in participants ≥80 YOA inconclusive due to low number of cases
- VE demonstrated for Severe LRTD based on clinical symptomatology definition but the numbers of accrued cases meeting the definition based on supportive therapy were too small to estimate efficacy precisely.
- Data are not currently available on:
  - Duration of vaccine effectiveness
  - VE in immunocompromised individuals

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VRBPAC February-March 2023

AVEXVY Safety

Summary: Safety

- A total of 15,745 RSVPreF3 recipients from four phase 3 studies were included in the Exposed Set. The median durations of follow-up was 7.2 months.
- RSVPreF3 is noted to have increased reactogenicity when compared to placebo, but the rates of Grade 3 reactions after vaccination in both groups were low (≤1.7%).
- Within 30 days post-vaccination a numerical imbalance was observed for events of atrial fibrillation in Study 006. FDA review of these events is ongoing.
- The frequency of SAEs reported up to 6 months post-vaccination was 4.0% and 4.5% in the RSVPreF3 and placebo groups.
- One (1) SAE (GBS) was considered by the study investigator and FDA to be related to vaccination.
- One (1) death due to ADEM considered by FDA as possibly related to FLU or RSVPreF3 vaccination.
- Up to the time of the DLPs at least one pIMD was reported by 0.4% and 0.3% of vaccine and placebo recipients, including 2 cases of ADEM in the Co-Ad group in Study 007
- A safety update was submitted for an extended safety follow-up at Month 6-12, containing SAE and pIMD data, and FDA review of these data are ongoing at this time.

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VRBPAC February-March 2023

AVEXVY
1. 10 yes
   2 no
   0 abstain
2. 12 yes
   0 no
   0 abstain

Voting Questions for VRBPAC

1. Are the available data adequate to support the safety of AREXVY (RSVPreF3+AS01$_E$) when administered to individuals 60 years of age and older for the prevention of lower respiratory tract disease caused by RSV?
   Please vote "Yes" or "No"
2. Are the available data adequate to support the effectiveness of AREXVY (RSVPreF3+AS01$_E$) for the prevention of lower respiratory tract disease caused by RSV in individuals 60 years of age and older?
   Please vote "Yes" or "No"

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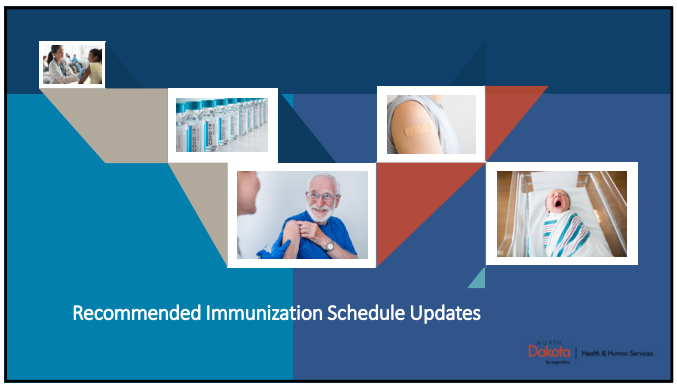

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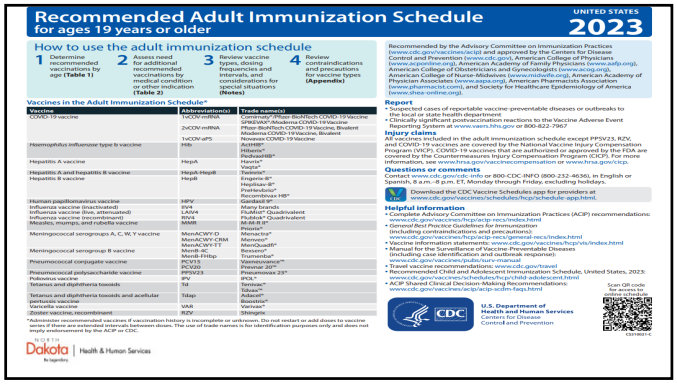

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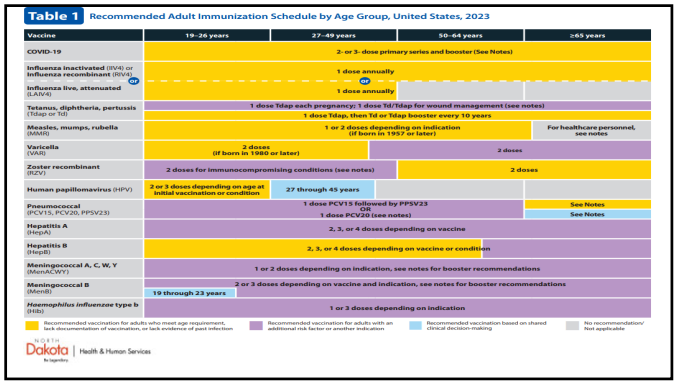

Table 1 Recommended Adult Immunization Schedule by Age Group, United States, 2023

Vaccine	19–26 years	27–49 years	50–64 years	≥65 years
COVID-19	2- or 3- dose primary series and booster (See Notes)			
Influenza inactivated (IIV4) or Influenza recombinant (RIV4)	1 dose annually			
Influenza live, attenuated (LAIV4)	1 dose annually			
Tetanus, diphtheria, pertussis (Tdap or Td)	1 dose Tdap each pregnancy; 1 dose Td/Tdap for wound management (see notes)			
	1 dose Tdap, then Td or Tdap booster every 10 years			
Measles, mumps, rubella (MMR)	1 or 2 doses depending on indication (if born in 1957 or later)			For healthcare personnel, see notes
Varicella (VAR)	2 doses (if born in 1980 or later)		2 doses	
Zoster recombinant (RZV)	2 doses for immunocompromising conditions (see notes)		2 doses	
Human papillomavirus (HPV)	2 or 3 doses depending on age at initial vaccination or condition	27 through 45 years		
Pneumococcal (PCV15, PCV20, PPSV23)	1 dose PCV15 followed by PPSV23 OR 1 dose PCV20 (see notes)			See Notes
				See Notes
Hepatitis A (HepA)	2, 3, or 4 doses depending on vaccine			
Hepatitis B (HepB)	2, 3, or 4 doses depending on vaccine or condition			
Meningococcal A, C, W, Y (MenACWY)	1 or 2 doses depending on indication, see notes for booster recommendations			
Meningococcal B (MenB)	2 or 3 doses depending on vaccine and indication, see notes for booster recommendations			
	19 through 23 years			
Haemophilus influenzae type b (Hib)	1 or 3 doses depending on indication			

Recommended vaccination for adults who meet age requirement, lack documentation of vaccination, or lack evidence of past infection | Recommended vaccination for adults with an additional risk factor or another indication | Recommended vaccination based on shared clinical decision-making | No recommendation/ Not applicable

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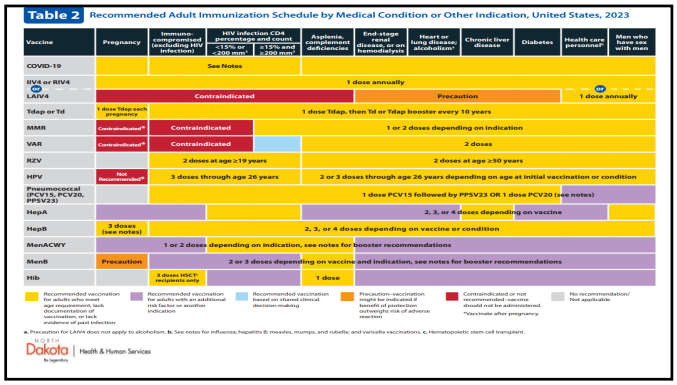

Table 2 Recommended Adult Immunization Schedule by Medical Condition or Other Indication, United States, 2023

Vaccine	Pregnancy	Immunocompromised (excluding HIV infection)	HIV infection CD4 percentage and count ≥15% or ≥200 mm³	HIV infection CD4 percentage and count <15% and <200 mm³	Asplenia, complement deficiencies	End-stage renal disease, or on hemodialysis	Heart or lung disease, alcoholism[a]	Chronic liver disease	Diabetes	Health care personnel[b]	Men who have sex with men
COVID-19		See Notes									
IIV4 or RIV4 OR LAIV4	1 dose annually										
	Contraindicated					Precaution				OR 1 dose annually	
Tdap or Td	1 dose Tdap each pregnancy	1 dose Tdap, then Td or Tdap booster every 10 years									
MMR	Contraindicated[c]	Contraindicated	1 or 2 doses depending on indication								
VAR	Contraindicated[c]	Contraindicated		2 doses							
RZV		2 doses at age ≥19 years		2 doses at age ≥50 years							
HPV	Not Recommended[c]	3 doses through age 26 years		2 or 3 doses through age 26 years depending on age at initial vaccination or condition							
Pneumococcal (PCV15, PCV20, PPSV23)	1 dose PCV15 followed by PPSV23 OR 1 dose PCV20 (see notes)										
HepA	2, 3, or 4 doses depending on vaccine										
HepB	3 doses (see notes)	2, 3, or 4 doses depending on vaccine or condition									
MenACWY	1 or 2 doses depending on indication, see notes for booster recommendations										
MenB	Precaution	2 or 3 doses depending on vaccine and indication, see notes for booster recommendations									
Hib	3 doses HSCT recipients only			1 dose							

Recommended vaccination for adults who meet age requirement, lack documentation of vaccination, or lack evidence of past infection | Recommended vaccination for adults with an additional risk factor or another indication | Recommended vaccination based on shared clinical decision-making | Precaution–vaccination might be indicated if benefits of vaccination outweighs risk of adverse reaction | Contraindicated or not recommended –vaccine should not be administered. *Vaccinate after pregnancy. | No recommendation/ 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.

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2023 Recommended Immunization Schedule Adult ages 19 years or older

Routine Immunization Schedule (table 1) updates:

- New COVID-19 vaccine row in yellow, indicating that it is routinely recommended for all adults
- MMR row – text in the column for ≥65 years referring providers to notes for considerations for healthcare providers
- Hepatitis A row – updated text "2, 3, or 4 doses depending on vaccine"

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2023 Recommended Immunization Schedule Adult ages 19 years or older

Immunization by Medical Indication Schedule (table 2) updates:

- New COVID-19 vaccine row in yellow, refers to notes regarding the immunocompromised and HIV positive
- Hepatitis A row – updated text "2, 3, or 4 doses depending on vaccine"

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2023 Recommended Immunization Schedule Adult ages 19 years or older

Vaccine Note updates:

- Edits to mirror the language between the Adult Schedule and the Child and Adolescent Schedule when possible
- Notes updated for COVID-19, HepB, Influenza, MMR, Meningococcal, Pneumococcal, Poliovirus, Tdap, and Zoster vaccines

Appendix updates:

- "Contraindications' column renamed to "Contraindicated or not recommended"
- Influenza (egg-based) row – history of egg allergy info moved from precautions column to notes
- Hep B row and human papillomavirus rows had language modifications regarding pregnancy

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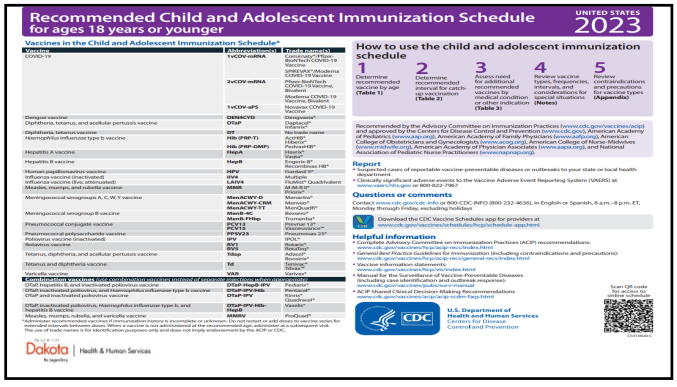

Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger

UNITED STATES 2023

Vaccines in the Child and Adolescent Immunization Schedule*

How to use the child and adolescent immunization schedule

1 Determine recommended vaccine by age (Table 1)

2 Determine recommended interval for catch-up vaccination (Table 2)

3 Assess need for additional recommended vaccines for high-risk condition or other indication (Table 3)

4 Review vaccine types, frequencies, intervals, and considerations for special situations (Notes)

5 Review contraindications and precautions for vaccine types (Appendix)

Report

Questions or comments

Helpful information

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

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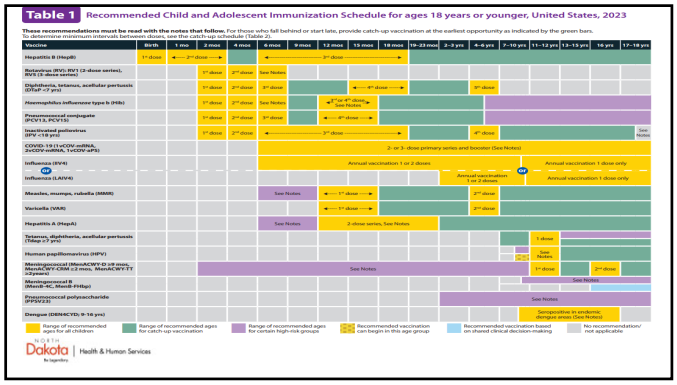

Table 1 Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2023

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).

Vaccine	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos	18 mos	19–23 mos	2–3 yrs	4–6 yrs	7–10 yrs	11–12 yrs	13–15 yrs	16 yrs	17–18 yrs
Hepatitis B (HepB)	1st dose	2nd dose			3rd dose												
Rotavirus (RV): RV1 (2-dose series), RV5 (3-dose series)			1st dose	2nd dose	See Notes												
Diphtheria, tetanus, acellular pertussis (DTaP: <7 yrs)			1st dose	2nd dose	3rd dose			4th dose			5th dose						
Haemophilus influenzae type b (Hib)			1st dose	2nd dose	See Notes		3rd or 4th dose, See Notes										
Pneumococcal conjugate (PCV13, PCV15)			1st dose	2nd dose	3rd dose		4th dose										
Inactivated poliovirus (IPV: <18 yrs)			1st dose	2nd dose	3rd dose					4th dose							See Notes
COVID-19 (1 vCOV-mRNA, 2vCOV-mRNA, 1vCOV-aPS)										2- or 3- dose primary series and booster (See Notes)							
Influenza (IIV4)							Annual vaccination 1 or 2 doses							Annual vaccination 1 dose only			
OR Influenza (LAIV4)											Annual vaccination 1 or 2 doses		OR	Annual vaccination 1 dose only			
Measles, mumps, rubella (MMR)					See Notes		1st dose					2nd dose					
Varicella (VAR)							1st dose					2nd dose					
Hepatitis A (HepA)					See Notes		2-dose series, See Notes										
Tetanus, diphtheria, acellular pertussis (Tdap ≥7 yrs)														1 dose			
Human papillomavirus (HPV)															See Notes		
Meningococcal (MenACWY-D ≥9 mos, MenACWY-CRM ≥2 mos, MenACWY-TT ≥2 years)					See Notes									1st dose		2nd dose	
Meningococcal B (MenB-4C, MenB-FHbp)															See Notes		
Pneumococcal polysaccharide (PPSV23)															See Notes		
Dengue (DEN4CYD; 9–16 yrs)															Seropositive in endemic dengue areas (See Notes)		

Range of recommended ages for all children | Range of recommended ages for catch-up vaccination | Range of recommended ages for certain high-risk groups | Recommended vaccination can begin in this age group | Recommended vaccination based on shared clinical decision-making | No recommendation/ not applicable

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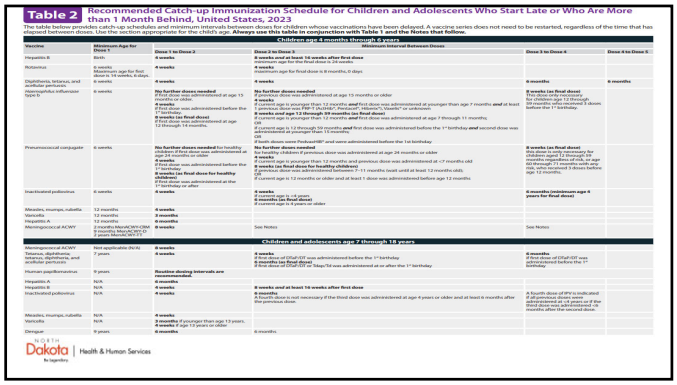

Table 2 Recommended Catch-up Immunization Schedule for Children and Adolescents Who Start Late or Who Are More than 1 Month Behind, United States, 2023

The table below provides catch-up schedules and minimum intervals between doses for children whose vaccinations have been delayed. A vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Use the section appropriate for the child's age. **Always use this table in conjunction with Table 1 and the Notes that follow.**

Vaccine	Minimum Age for Dose 1	Minimum Interval Between Doses			
		Dose 1 to Dose 2	Dose 2 to Dose 3	Dose 3 to Dose 4	Dose 4 to Dose 5
Children age 4 months through 6 years					
Hepatitis B	Birth	4 weeks	8 weeks and at least 16 weeks after first dose Minimum age for the final dose is 24 weeks		
Rotavirus	6 weeks Maximum age for first dose is 14 weeks, 6 days.	4 weeks	4 weeks Maximum age for final dose is 8 months, 0 days		
Diphtheria, tetanus, and acellular pertussis	6 weeks	4 weeks	4 weeks	6 months	6 months
Haemophilus influenzae type b	6 weeks	No further doses needed If first dose was administered at age 15 months or older 4 weeks If first dose was administered before the 1st birthday 8 weeks (as final dose) If first dose was administered at age 12 through 14 months.	No further doses needed If first dose was administered at age 15 months or older 4 weeks If current age is younger than 12 months and first dose was administered at younger than age 7 months and at least 4 weeks has elapsed since the first dose; or if unknown. 8 weeks and age 12 through 59 months (as final dose) If current age is younger than 12 months and first dose was administered at age 7 through 11 months; OR If current age is 12 through 59 months and first dose was administered before the 1st birthday and second dose was administered at younger than 15 months; OR If both doses were PedvaxHIB® and were administered before the 1st birthday	8 weeks (as final dose) This dose is only necessary for children age 12 through 59 months who received 3 doses before the 1st birthday.	
Pneumococcal conjugate	6 weeks	No further doses needed for healthy children if first dose was administered at age 24 months or older 4 weeks If first dose was administered before the 1st birthday 8 weeks (as final dose for healthy children) If first dose was administered at the age 12 through 23 months	No further doses needed If first dose was administered at age 24 months or older 4 weeks If current age is younger than 12 months and previous dose was administered at <7 months old 8 weeks (as final dose) If previous dose was administered between 7–11 months (wait until at least 12 months old) OR If current age is 12 months or older and at least 1 dose was administered before age 12 months	8 weeks (as final dose) This dose is only necessary for children aged 12 through 59 months regardless of risk, or age 5 through 18 years who are high risk, who received 3 doses before age 12 months.	
Inactivated poliovirus	6 weeks	4 weeks	4 weeks If current age is <4 years 4 weeks (as final dose) If current age is 4 years or older	6 months (minimum age 4 years for final dose)	
Measles, mumps, rubella	12 months	4 weeks			
Varicella	12 months	3 months			
Hepatitis A	12 months	6 months			
Meningococcal ACWY	2 months MenACWY-CRM 9 months MenACWY-D 2 years MenACWY-TT	8 weeks	See Notes	See Notes	
Children and adolescents age 7 through 18 years					
Meningococcal ACWY Tetanus, diphtheria, tetanus, diphtheria, and acellular pertussis	Not applicable (N/A) 7 years	8 weeks 4 weeks	4 weeks If first dose of DTaP/IDT was administered before the 1st birthday 8 weeks (as final dose) If first dose of DTaP/IDT or Tdap/Td was administered at or after the 1st birthday	6 months If first dose of DTaP/IDT was administered before the 1st birthday	
Human papillomavirus	9 years	Routine dosing intervals are recommended.			
Hepatitis A	N/A	6 months			
Hepatitis B	N/A	4 weeks	8 weeks and at least 16 weeks after first dose		
Inactivated poliovirus	N/A	4 weeks	4 weeks A booster dose is not necessary if the third dose was administered at age 4 years or older and at least 6 months after the previous dose.	A fourth dose of IPV is indicated if all previous doses were administered at <4 years or if the interval between the third and fourth months after the second dose.	
Measles, mumps, rubella	N/A	4 weeks			
Varicella	N/A	3 months if younger than age 13 years. 4 weeks if age 13 years or older			
Dengue	9 years	6 months	6 months		

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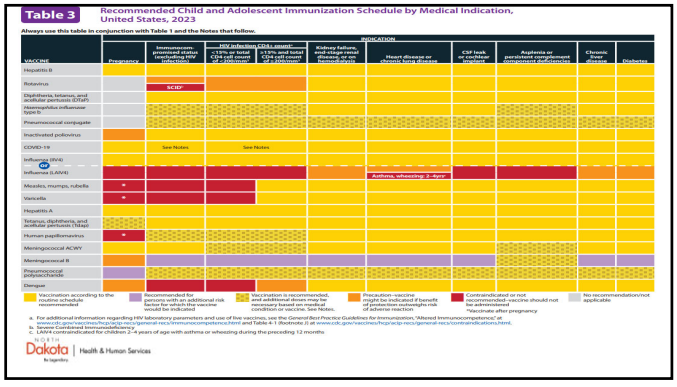

Table 3 Recommended Child and Adolescent Immunization Schedule by Medical Indication, United States, 2023

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

VACCINE	INDICATION										
	Pregnancy	Immunocompromised status (excluding HIV infection)	HIV infection CD4+ count[a]: <15% or total <200 cells/mm³ (<14 years) or <200 cells/mm³ (≥14 years)	HIV infection CD4+ count[a]: ≥15% and total ≥200 cells/mm³ (<14 years) or ≥200 cells/mm³ (≥14 years)	Kidney failure, end-stage renal disease (ESRD), kidney transplant	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[b]								
Diphtheria, tetanus, and acellular pertussis (DTaP)										
Haemophilus influenzae type b										
Pneumococcal conjugate										
Inactivated poliovirus										
COVID-19		See Notes	See Notes							
Influenza (IIV4)										
OR Influenza (LAIV4)						Asthma, wheezing: 2–4yrs[c]				
Measles, mumps, rubella	*									
Varicella	*									
Hepatitis A										
Tetanus, diphtheria, and acellular pertussis (Tdap)										
Human papillomavirus	*									
Meningococcal ACWY										
Meningococcal B										
Pneumococcal polysaccharide										
Dengue										

Vaccination according to the routine schedule recommended | Recommended for persons with an additional risk factor for which the vaccine would be indicated | Vaccination is recommended, and additional doses may be necessary based on medical condition or vaccine. See Notes. | Precaution–vaccine might be indicated if benefit of protection outweighs risk of adverse reaction | Contraindicated or not recommended–vaccine should not be administered | No recommendation/not applicable

*Vaccinate after pregnancy

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 illustrate.ti at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.
b. Severe Combined Immunodeficiency
c. LAIV4 contraindicated for children 2–4 years of age with asthma or wheezing during the preceding 12 months

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2023 Recommended Immunization Schedule Child and Adolescent ages 18 years or younger

Routine Immunization Schedule (table 1) updates:

- New COVID-19 vaccine row in yellow, indicating that it is routinely recommended for 6 months to 18 years
- Pneumococcal conjugate row – PCV 15 added
- IPV row – prompts healthcare providers to review the Notes section for people age 18 years

Catch-up Immunization Schedule (table 2) updates:

- Pneumococcal conjugate row – language for the minimum interval between doses 3 and 4 revised

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2023 Recommended Immunization Schedule Child and Adolescent ages 18 years or younger

Immunization by Medical Indication Schedule (table 3) updates:

- New COVID-19 vaccine row in yellow, refers to notes regarding the immunocompromised and HIV positive

Vaccine Note updates:

- Edits to mirror the language between the Adult Schedule and the Child and Adolescent Schedule when possible
- Notes updated for COVID-19, Dengue, HepB, Influenza, MMR, MenACWY, MenB, Pneumococcal, and Poliovirus vaccines

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2023 Recommended Immunization Schedule Child and Adolescent ages 18 years or younger

Appendix updates:

- "Contraindications' column renamed to "Contraindicated or not recommended"
- Influenza (egg-based) row – history of egg allergy with symptoms other than hives info moved from precautions column to notes
- Dengue row – lack of lab confirmation of previous dengue virus infection is a contraindication added
- Hep B row and human papillomavirus rows had language modifications regarding pregnancy
- MMR row – MMRV added, precaution for using MMRV of personal or family history of seizure added
- Varicella row – precautions for MMR/MMRV should be reviewed if using MMRV

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Post-Test

- Post-test
  - Nurses interested in continuing education credit, visit https://ndhealth.co1.qualtrics.com/jfe/form/SV_6LH8Fmq6rIRNOiq
  - Successfully complete the five-question post-test to receive your certificate
  - Credit for this session will not expire until April 22, 2023.
- This presentation will be posted to our website: www.hhs.nd.gov/immunizations

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Immunization Update:

ACIP and VRBPAC Meeting Reviews

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Immunization Update: ACIP and VRBPAC Meeting Reviews

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