A DOSE OF IMMUNIZATION INFORMATION

EMILY KRYGER, PHARMD, BCGP, FASCP

PACAH 2024 FALL SUMMIT

SPEAKER: EMILY KRYGER, PHARMD, BCGP, FASCP

Dr. Emily Kryger is owner of PharmRecs LLC, a consulting company working with nursing facilities, pharmacies, provider practices, and health care organizations for post-acute care medication management. Dr. Kryger also works as a clinical pharmacist for the UPMC St. Margaret Geriatric Care Center & medical education department. She is a graduate of the University of Pittsburgh School of Pharmacy and a Board-Certified Geriatric Pharmacist. Dr. Kryger is a fellow of the American Society of Consultant Pharmacists (ASCP). She is past president and ongoing board member of the ASCP-Pennsylvania chapter and a member of the ASCP Government and Antimicrobial Stewardship & Infection control committees.

DISCLOSURES

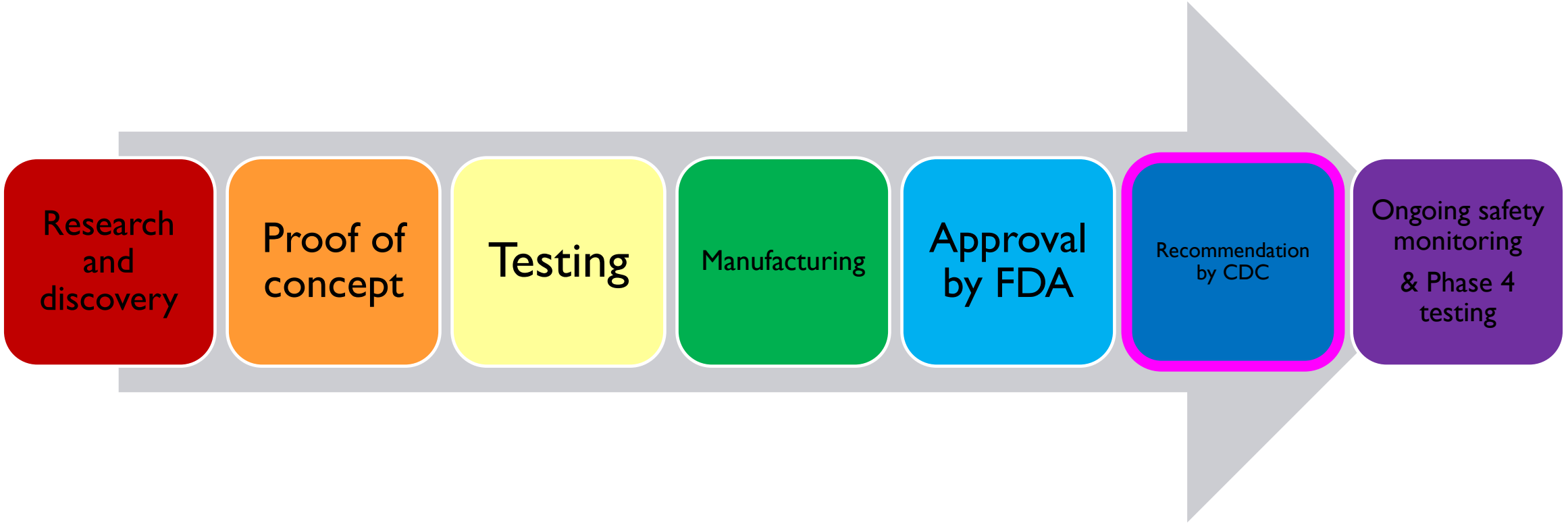
- Emily Kryger is a consultant for Omnis Health, a diabetes testing supply company.

LEARNING OBJECTIVES

1. Explain the vaccine approval & recommendation process in the United States
2. Identify nursing facility requirements & quality measures related to immunizations
3. Discuss the CDC immunization schedule for older adults

LEARNING OBJECTIVE 1: EXPLAIN THE VACCINE APPROVAL & RECOMMENDATION PROCESS IN THE UNITED STATES

HOW VACCINES ARE DEVELOPED AND APPROVED FOR USE



https://www.cdc.gov/vaccines/basics/test-approve.html

STEPS OF VACCINE DEVELOPMENT AND APPROVAL

- Research & Discovery: explore ideas/opportunities for potential vaccines
- Proof of concept
  - Study ability of vaccine to cause immune response in animals
  - Adjust vaccine to make it more effective
- Testing/Clinical Trials - Focus: safety (side effects) & efficacy (immune response)
  - Phase 1 (20-100 people)
  - Phase II (hundreds of people)
    - Participants with characteristics similar to intended recipients
    - Diverse backgrounds to ensure representation of different populations
  - Phase III (thousands of people)
    - Confirm efficacy of vaccine
    - Look for less common side effects
    - Collect robust information on safe use
- Manufacturing: FDA evaluates manufacturing process for vaccines (Facility inspection, lot consistency)

STEPS OF VACCINE DEVELOPMENT AND APPROVAL CONTINUED

- Approval by FDA
  - Manufacturer submits Biological License Application (BLA)- trial data, manufacturing information, prescribing information
  - **FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC)** provides input on scientific data to look at safety, effectiveness, & use of the vaccine and makes a recommendation to the FDA commissioner for authorization.
  - FDA licenses vaccine
  - An Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies
- Recommendation by CDC
  - **CDC's Advisory Committee on Immunization Practices (ACIP)** makes a recommendation for use of the vaccines in the US. CDC Director decides whether to approve the recommendation.

*ACIP only makes recommendations for vaccines that are approved by FDA

STEPS OF VACCINE DEVELOPMENT AND APPROVAL CONTINUED

- Monitoring safety after approval
  - The Vaccine Adverse Event Reporting System (VAERS)
    - Early warning system that helps CDC and FDA monitor problems following vaccination
    - Anyone can report suspected vaccine reactions and issues to VAERS
  - Vaccine Safety Datalink
    - Collaboration between CDC and several health organizations that allows ongoing monitoring and proactive searches of vaccine-related data.
    - When ACIP recommends new vaccines for use in the United States or makes changes to a vaccine's recommendation, VSD will monitor the safety of these vaccines.
  - Clinical Immunization Safety Assessment (CISA) Project
    - Partnership between CDC and several medical centers that conduct clinical research on vaccine-related health risks
  - Phase 4 clinical trials
    - Ongoing study to evaluate the new vaccine's safety and effectiveness over a longer period of time

ACIP RECOMMENDATIONS

- The ACIP develops recommendations on how to use vaccines to control disease in the United States.
- ACIP holds three regular meetings each year (February, June, October), in addition to emergency sessions
- The Committee's recommendations are forwarded to CDC's Director and once adopted become official CDC policy. These recommendations are then published in CDC's Morbidity and Mortality Weekly Report (MMWR).
- CDC sets the U.S immunization schedules based upon ACIP recommendations
  - childhood, adolescent, and adult immunization schedules
    - Routine, catch-up, and risk based
    - Shared Clinical Decision Making-Recommendations

https://www.cdc.gov/vaccines/acip/recommendations.html

ACIP SHARED CLINICAL DECISION-MAKING RECOMMENDATIONS

- Not recommended for everyone in a particular age group or everyone in an identifiable risk group
  - individually based and informed by a decision process between the health care provider and the patient or parent/guardian.
    - CDC defines a health care provider as anyone who provides or administers vaccines: primary care physicians, specialists, physician assistants, nurse practitioners, registered nurses, and pharmacists.

https://www.cdc.gov/vaccines/acip/acip-scdm-faqs.html

ACIP SHARED CLINICAL DECISION-MAKING RECOMMENDATIONS

- ACIP has four recommendations for vaccination based on shared clinical decision-making:
  - Meningococcal B (MenB) vaccination for adolescents and young adults aged 16–23 years
  - **Hepatitis B (HepB) vaccination for adults aged 60 years and older with diabetes mellitus**
  - Human papillomavirus (HPV) vaccination for adults aged 27–45 years
  - **Pneumococcal conjugate vaccination (PCV20) for adults aged 65 years and older who have completed the recommended vaccine series with both PCV13 (at any age) and PPSV23 (which was administered at age ≥65 years)**

https://www.cdc.gov/vaccines/acip/acip-scdm-faqs.html

WHAT ACIP CONSIDERS IN THE VACCINE RECOMMENDATION PROCESS

- The safety and effectiveness of the vaccine
- The severity of the disease
- The number of people who get the disease if there is no vaccine
- How well a vaccine works for people of different ages
- How practical the recommendations are to put into practice

https://www.cdc.gov/vaccines/acip/committee/role-vaccine-recommendations.html

LEARNING OBJECTIVE 2: IDENTIFY NURSING FACILITY REQUIREMENTS & QUALITY MEASURES RELATED TO IMMUNIZATIONS

§483.80(D) INFLUENZA AND PNEUMOCOCCAL IMMUNIZATIONS

F883 CMS STATE OPERATIONS MANUAL APPENDIX PP

https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/downloads/appendix-pp-state-operations-manual.pdf

§483.80(D)(1) INFLUENZA

The facility must develop policies and procedures to ensure that-

- (i) Before offering the influenza immunization, each **resident or the resident's representative receives education regarding the benefits and potential side effects of the immunization**;
- (ii) Each resident is **offered an influenza immunization October 1 through March 31 annually**, unless the immunization is medically contraindicated or the resident has already been immunized during this time period;
- (iii) The resident or the resident's representative **has the opportunity to refuse immunization**;
- (iv) The resident's medical record includes **documentation** that indicates, at a minimum, the following: (A) That the resident or resident's representative was **provided education** regarding the benefits and potential side effects of influenza immunization; and (B) That the resident either **received the influenza immunization or did not receive the influenza immunization due to medical contraindications or refusal.**

§483.80(D)(2) PNEUMOCOCCAL DISEASE

The facility must develop policies and procedures to ensure that-

- (i) Before offering the pneumococcal immunization, each resident or the resident's representative receives **education regarding the benefits and potential side effects of the immunization;**
- (ii) Each resident is **offered a pneumococcal immunization,** unless the immunization is medically contraindicated or the resident has already been immunized;
- (iii) The resident or the resident's representative **has the opportunity to refuse immunization**; and
- (iv) The resident's medical record includes **documentation** that indicates, at a minimum, the following: (A) That the resident or resident's representative was **provided education** regarding the benefits and potential side effects of pneumococcal immunization; and (B) That the **resident either received the pneumococcal immunization or did not receive the pneumococcal immunization due to medical contraindications or refusal.**

§483.80(D)(3) COVID-19 IMMUNIZATIONS
F887 COVID-19 IMMUNIZATION
F884 REPORTING – NATIONAL HEALTHCARE SAFETY NETWORK (NHSN)

The LTC facility must develop and implement policies and procedures to ensure all the following:

- (i) When COVID-19 vaccine is available to the facility, each resident and staff member is offered the COVID-19 vaccine unless the immunization is medically contraindicated or the resident or staff member has already been immunized;
- (ii) Before offering COVID-19 vaccine, all staff members are provided with education regarding the benefits and risks and potential side effects associated with the vaccine;
- (iii) Before offering COVID-19 vaccine, each resident or the resident representative receives education regarding the benefits and risks and potential side effects associated with the COVID-19 vaccine;
- (iv) In situations where COVID-19 vaccination requires multiple doses, the resident, resident representative, or staff member is provided with current information regarding those additional doses, including any changes in the benefits or risks and potential side effects, associated with the COVID-19 vaccine, before requesting consent for administration of any additional doses.
- (v) The resident, resident representative, or staff member has the opportunity to accept or refuse a COVID-19 vaccine, and change their decision; and (vi) The resident's medical record includes documentation that indicates, at a minimum, the following:
  - (A) That the resident or resident representative was provided education regarding the benefits and potential risks associated with COVID-19 vaccine; and
  - (B) Each dose of COVID-19 vaccine administered to the resident, or (C) If the resident did not receive the COVID-19 vaccine due to medical contraindications or refusal.
- (vii) The facility maintains documentation related to staff COVID-19 vaccination that includes at a minimum, the following:
  - (A) That staff were provided education regarding the benefits and potential risks associated with COVID-19 vaccine;
  - (B) Staff were offered the COVID-19 vaccine or information on obtaining COVID-19 vaccine; and (C) The COVID-19 vaccine status of staff and related information as indicated by NHSN.

MEDICARE AND MEDICAID PROGRAMS
COVID-19 VACCINE REQUIREMENTS FOR LONG-TERM CARE (LTC) FACILITIES
POLICY AND REGULATORY CHANGES TO THE OMNIBUS COVID-19 HEALTH CARE STAFF VACCINATION REQUIREMENTS

- Interim rule effective May 20,2021
- Final rule effective August 5, 2023
- **Finalized requirement for facilities to provide education about COVID–19 vaccines and to offer COVID–19 vaccines to residents and staff.**

https://www.federalregister.gov/documents/2023/06/05/2023-11449/medicare-and-medicaid-programs-policy-and-regulatory-changes-to-the-omnibus-covid-19-health-care

https://www.cms.gov/files/document/qso-21-19-nh.pdf

https://www.federalregister.gov/documents/2021/05/13/2021-10122/medicare-and-medicaid-programs-covid-19-vaccine-requirements-for-long-term-care-ltc-facilities-and

F881 INFECTION PREVENTION AND CONTROL PROGRAM

- §483.80(a) Infection prevention and control program. The facility must establish an infection prevention and control program (IPCP) that must include, at a minimum, the following elements:
- §483.80(a)(3) An antibiotic stewardship program that includes antibiotic use protocols and a system to monitor antibiotic use.

SNF 5-STAR RATING

Overall rating

★★★★★

Much above average

The overall rating is based on a nursing home's performance on 3 sources: health inspections, staffing, and quality measures.

Learn how Medicare calculates this rating

Health inspections

★★★★★

Much above average

View Inspection Results

Staffing

★★★★★

Much above average

View Staffing Information

Quality measures

★★★★★

Much above average

View Quality Measures

https://www.medicare.gov/care-compare/

FLU & PNEUMONIA PREVENTION MEASURES SHORT-STAY RESIDENTS

Percentage of short-stay residents who needed and got a flu shot for the current flu season

Higher percentages are better

80.5%

National average: 76.2%

Pennsylvania average: 70.1%

Percentage of healthcare personnel who got a flu shot for the current season

Higher percentages are better

72.9%

National average: 47%

Percentage of short-stay residents who needed and got a vaccine to prevent pneumonia

Higher percentages are better

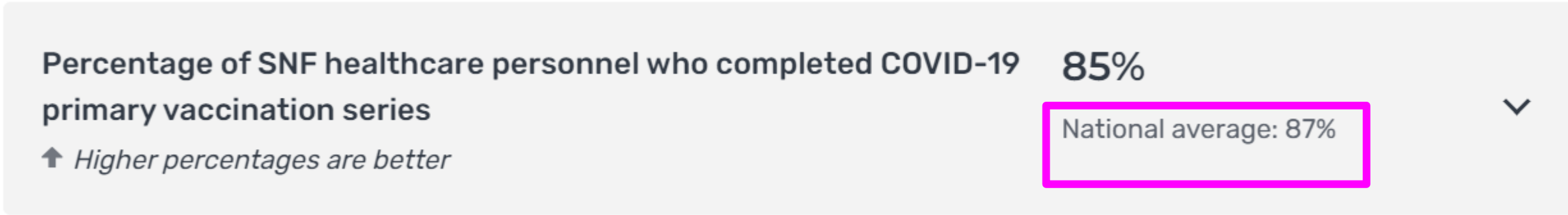
88.2%

National average: 79.7%

Pennsylvania average: 70.3%

https://www.medicare.gov/care-compare/

ADDITIONAL QUALITY MEASURES
SHORT-STAY RESIDENTS



https://www.medicare.gov/care-compare/

FLU & PNEUMONIA PREVENTION MEASURES LONG-STAY RESIDENTS

Percentage of long-stay residents who needed and got a flu shot for the current flu season *Higher percentages are better* National average: 94.8% PA average: 93.8%	84.6%
Percentage of long-stay residents who needed and got a vaccine to prevent pneumonia *Higher percentages are better* National average: 92% PA average: 87.3%	89.3%

https://www.medicare.gov/care-compare/

COVID-19 VACCINATION RATES

Residents who are up-to-date on their vaccines

↑ *Higher percentages are better*

24.7%

National average: 41.7%

Pennsylvania average: 45.7%

Staff who are up-to-date on their vaccines

↑ *Higher percentages are better*

7.7%

National average: 12.2%

Pennsylvania average: 13.2%

https://www.medicare.gov/care-compare/

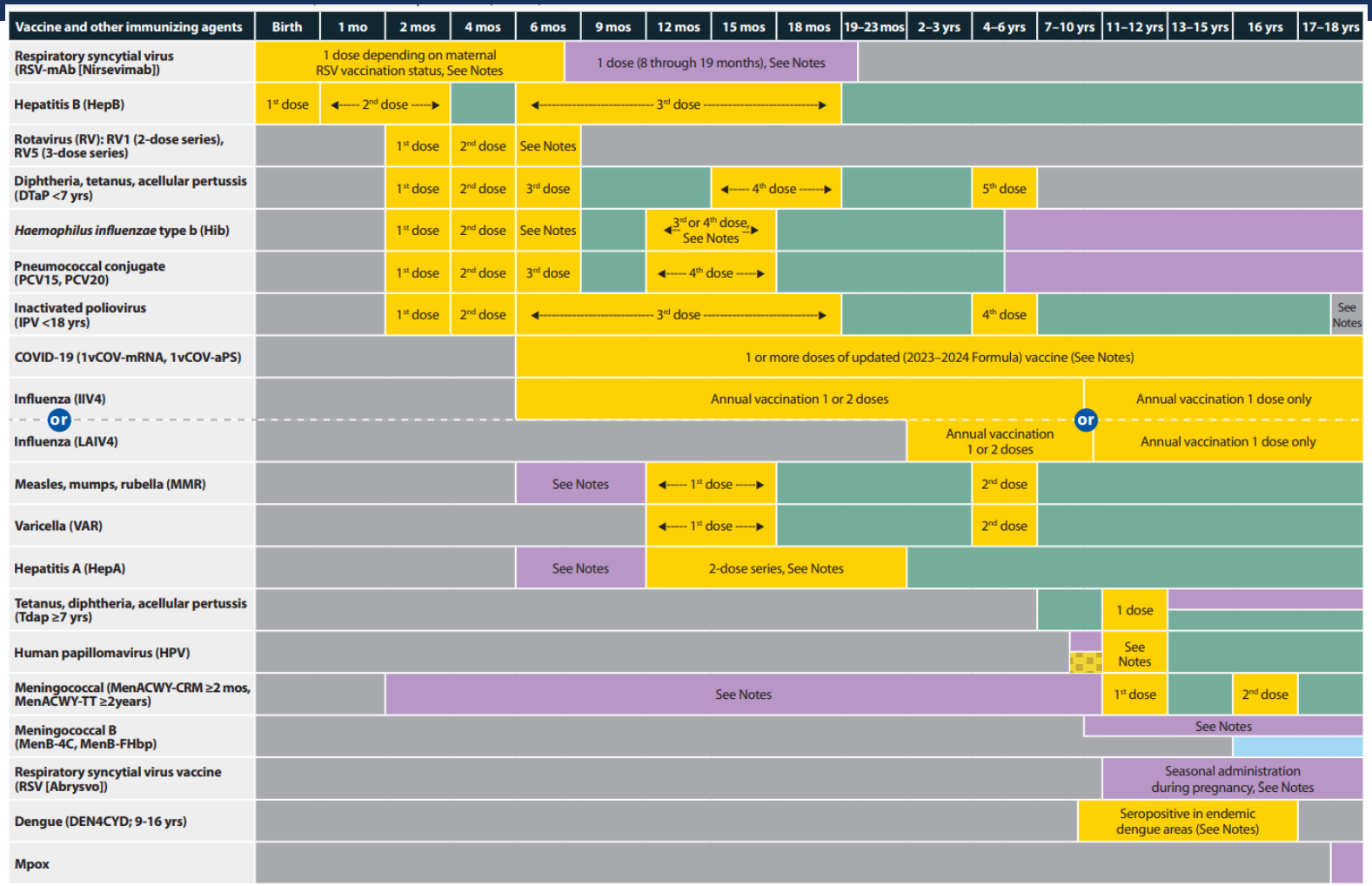
LEARNING OBJECTIVE 3: DISCUSS THE CDC IMMUNIZATION SCHEDULE FOR OLDER ADULTS

JOKE TIME

Why do anti vaxxers hate vaccine jokes?

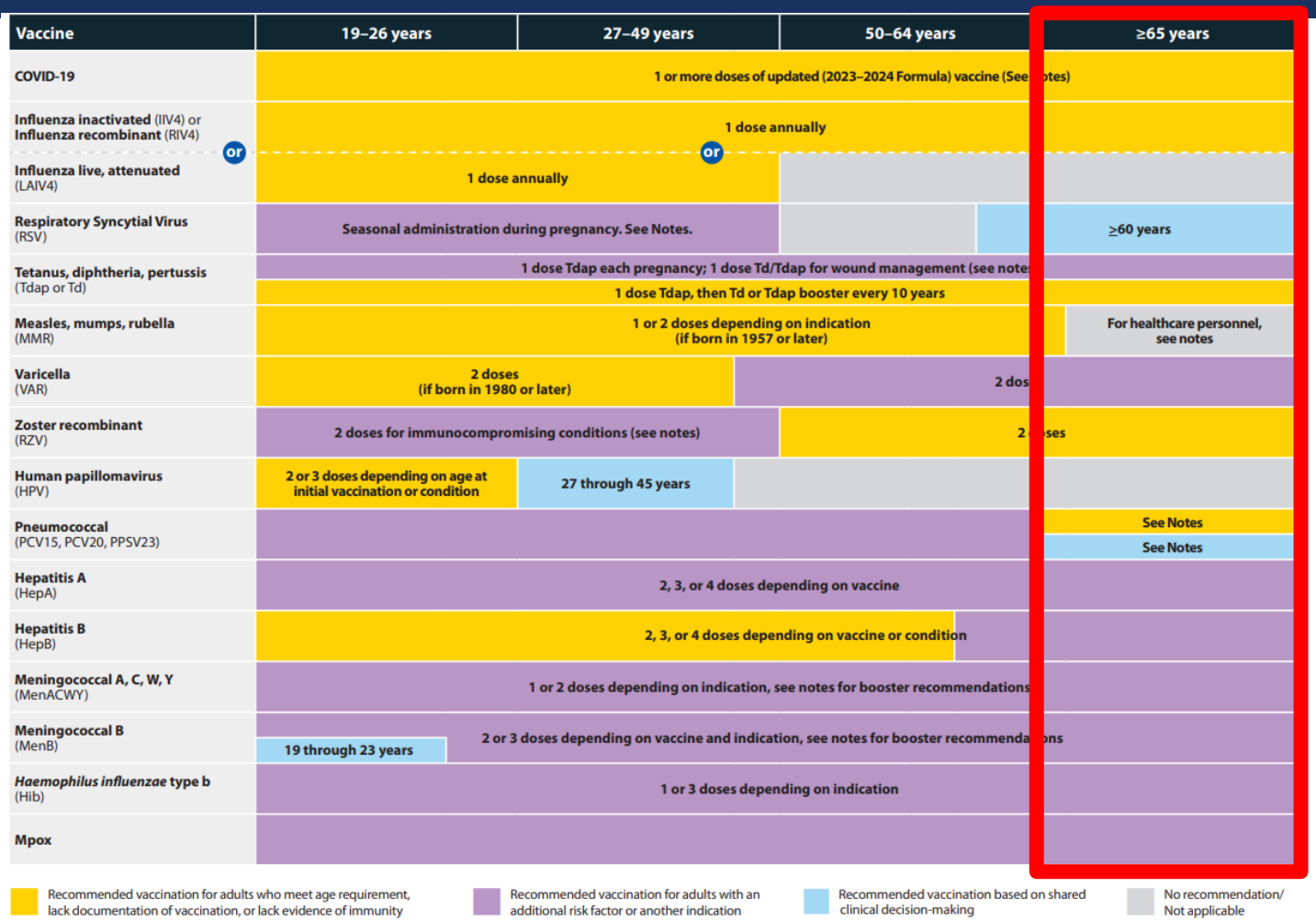
They never get them.

RECOMMENDED CHILD AND ADOLESCENT IMMUNIZATION SCHEDULE FOR AGES 18 YEARS OR YOUNGER, UNITED STATES, 2024



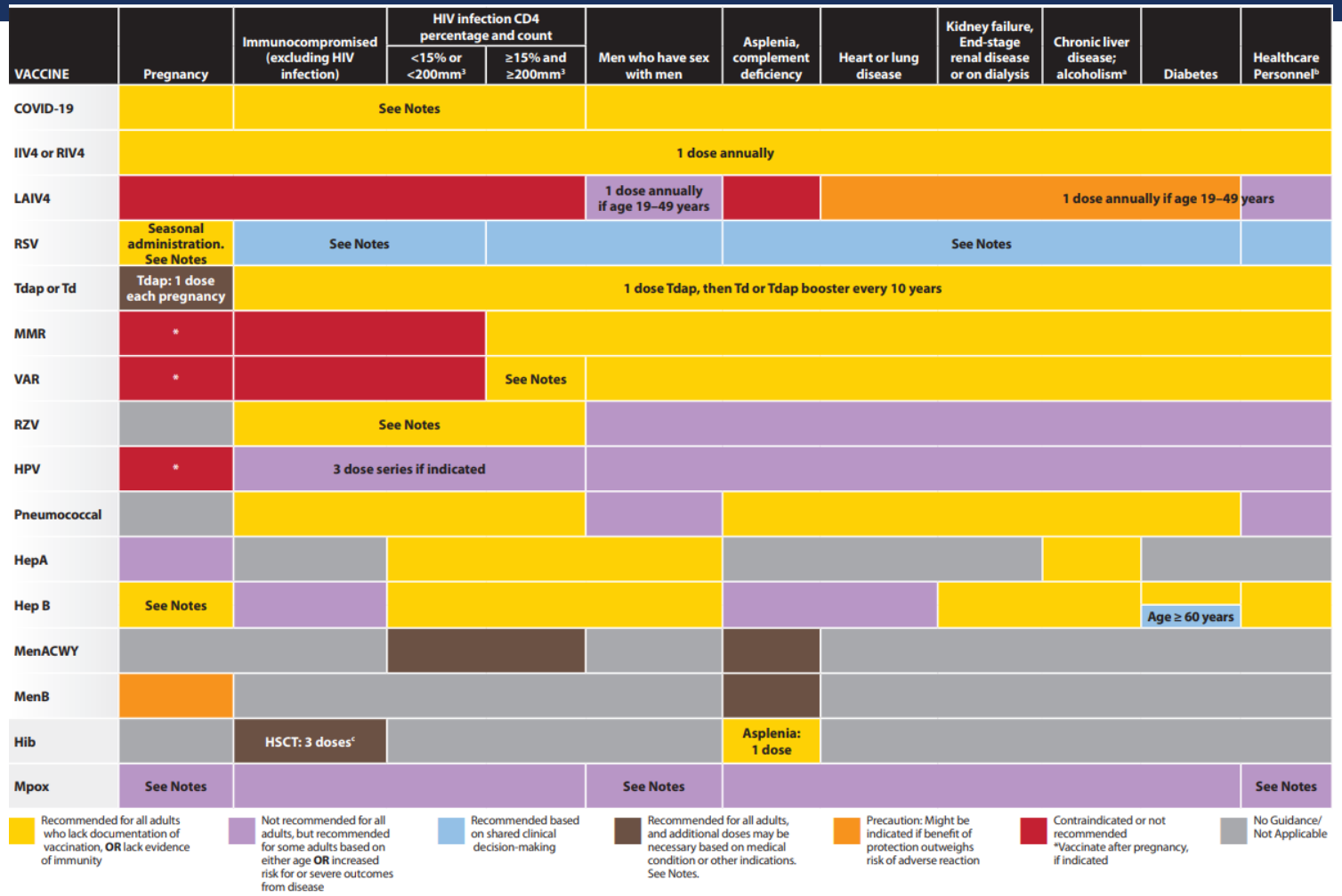
https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf

RECOMMENDED ADULT IMMUNIZATION SCHEDULE FOR AGES 19 YEARS OR OLDER, UNITED STATES, 2024



https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf

RECOMMENDED ADULT IMMUNIZATION SCHEDULE BY MEDICAL CONDITION OR OTHER INDICATION, UNITED STATES, 2024



https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf

CDC ADULT IMMUNIZATION SCHEDULE ADDENDUM

- https://www.cdc.gov/vaccines/schedules/hcp/imz/adult-schedule-addendum.html

COVID-19 (Moderna, Pfizer-BioNTech, Novavax)	ACIP recommends 2024-2025 COVID-19 vaccines as authorized or approved by FDA in persons ≥6 months of age.	June 27, 2024
Influenza	• ACIP reaffirms the recommendation for routine annual influenza vaccination of all persons aged ≥6 months who do not have contraindications. • ACIP recommends high-dose inactivated (HD-IIV3) and adjuvanted inactivated (aIIV3) influenza vaccines as acceptable options for influenza vaccination of solid organ transplant recipients aged 18 through 64 years who are on immunosuppressive medication regimens, without a preference over other age-appropriate IIV3s or RIV3.	June 27, 2024
Pneumococcal conjugate vaccine	ACIP recommends PCV21 as an option for adults aged ≥19 years who currently have a recommendation to receive a dose of PCV.	June 27, 2024
Respiratory syncytial virus vaccine (RSV)	• ACIP recommends adults 75 years of age and older receive a single dose of RSV vaccine.[a,b] • ACIP recommends adults 60–74 years of age and older who are at increased risk of severe RSV disease receive a single dose of RSV vaccine.[a,b]	June 26, 2024

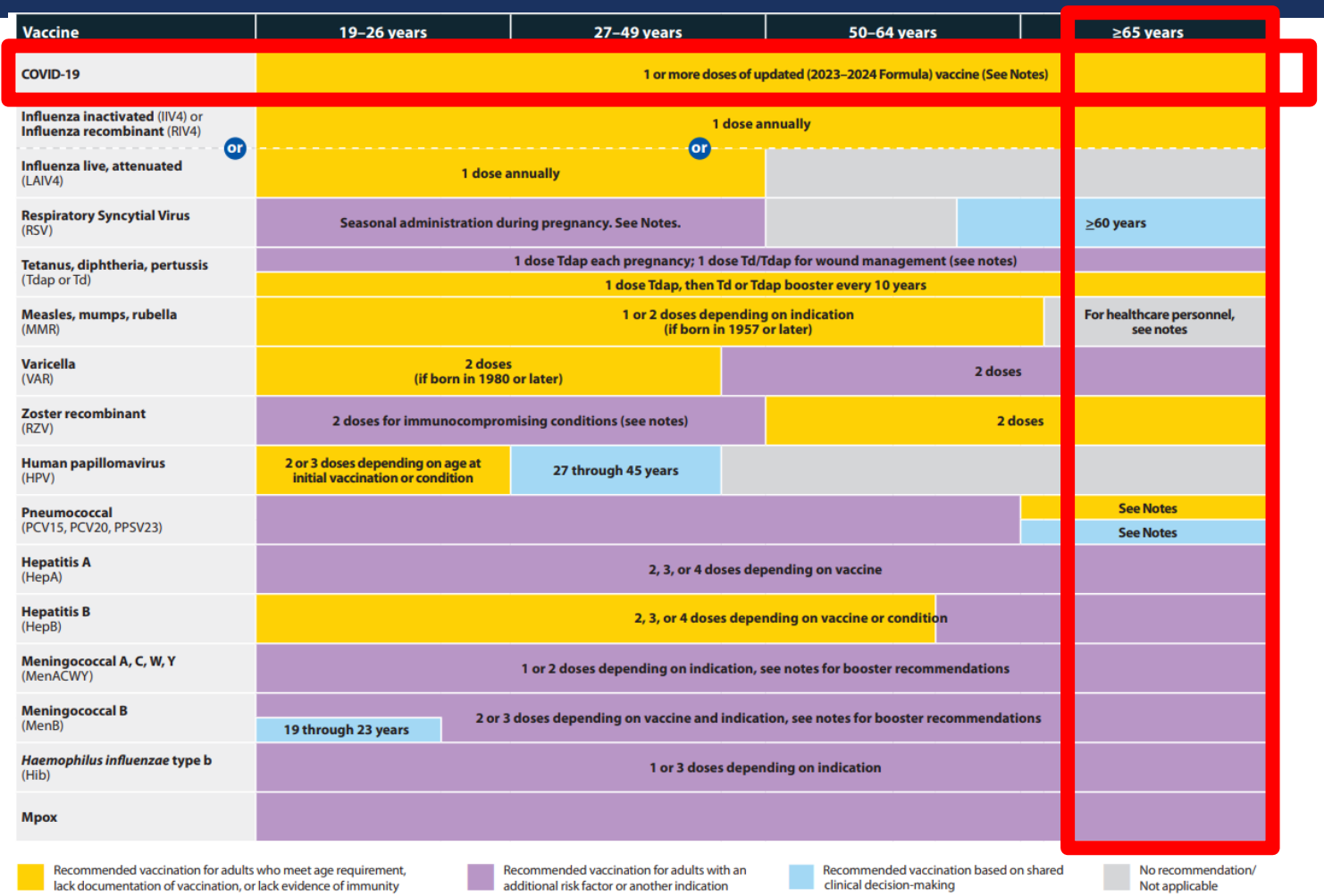
CDC ADULT IMMUNIZATION SCHEDULE LEGEND

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

https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf

COVID-19

RECOMMENDED ADULT IMMUNIZATION SCHEDULE FOR AGES 19 YEARS OR OLDER, UNITED STATES, 2024



https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf

ADULT IMMUNIZATION SCHEDULE ADDENDUM (UPDATED JUNE 27, 2024)

- ACIP recommends 2024-2025 COVID-19 vaccines as authorized or approved by FDA in persons ≥6 months of age.

https://www.cdc.gov/vaccines/schedules/hcp/imz/adult-schedule-addendum.html

2024-2025 COVID-19 VACCINES

- FDA advised manufacturers to develop **monovalent JN.1 lineage** COVID-19 vaccines, with a preference for the **KP.2 strain**
- **The JN.1 variant** is antigenically distinct from the XBB.1.5 variant, which was the target of the 2023-2024 monovalent COVID-19 vaccines

U.S. COVID-19 VACCINE PRODUCT INFORMATION

- There are two types of COVID-19 vaccines currently available in the United States:
  - mRNA vaccine (Pfizer, Moderna)
  - Protein subunit vaccine (Novavax)
  - There is no preferential recommendation for the use of any one COVID-19 vaccine over another when more than one licensed or authorized, recommended, and age-appropriate vaccine is available.
- Ordering COVID-19 vaccines through the government stopped in August 2023. COVID-19 vaccines are now commercialized products and obtained through regular ordering channels.

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/overview-COVID-19-vaccines.html
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html#novavax-people-65-older

2024-2025 COVID-19 VACCINE COVERAGE

- Due to the Congressional funding rescissions, the Bridge Access Program sunset in August 2024, and will not be available to cover the 2024-2025 COVID-19 vaccine

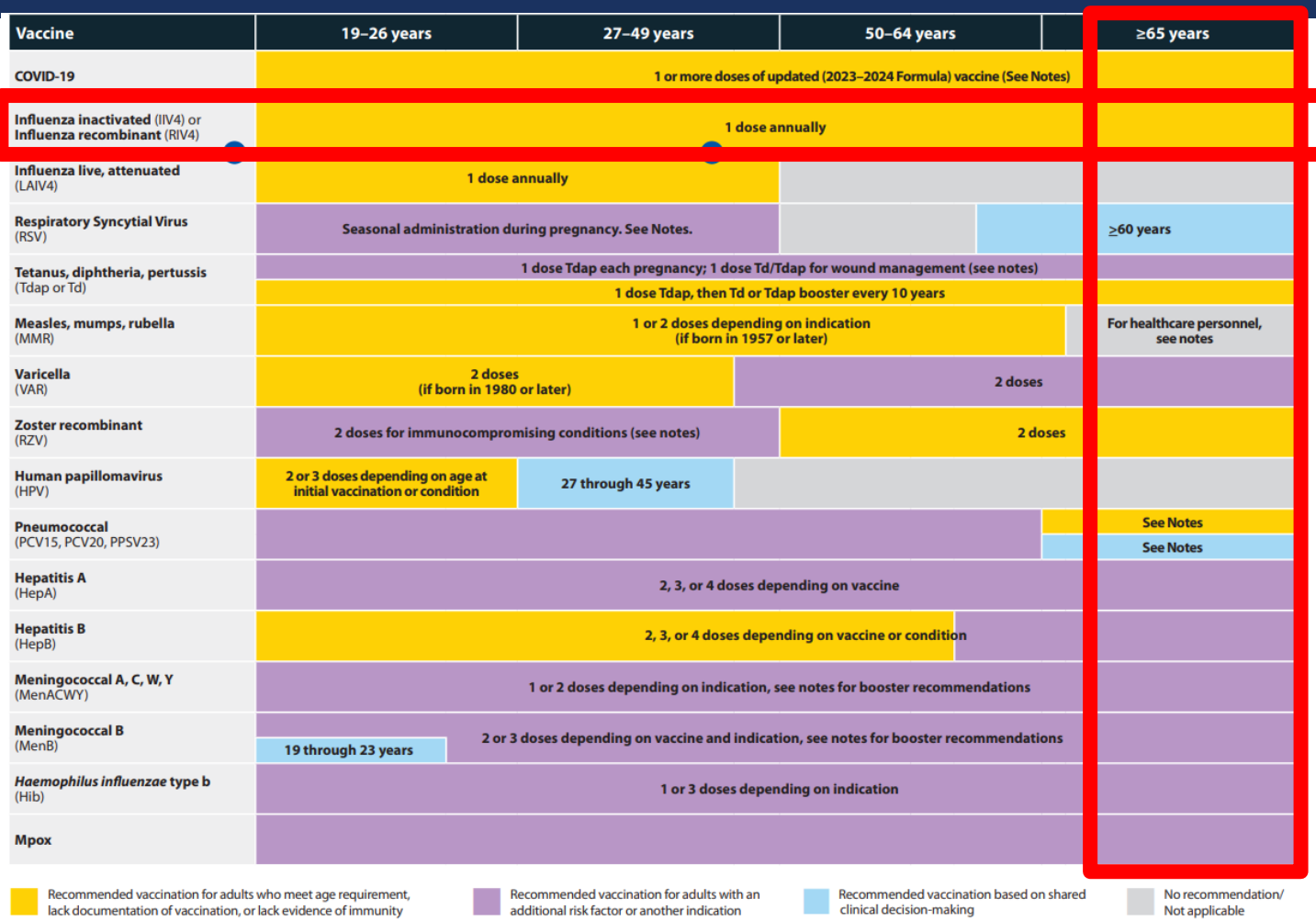
HIGHER RISK FOR SEVERE COVID-19 MORBIDITY & MORTALITY

- Age is the strongest risk factor for severe COVID-19 outcomes
  - Compared with ages 18–29 years, the risk of death is 25 times higher in those ages 50–64 years, 60 times higher in those ages 65–74 years, 140 times higher in those ages 75–84 years, and 340 times higher in those ages 85+ years
  - Residents of long-term care facilities are also at increased risk, making up less than 1% of the U.S. population but accounting for more than 35% of all COVID-19 deaths
- Underlying medical conditions (Pregnancy, Immunocompromised, Chronic Conditions)
- People from racial and ethnic minority groups are dying from COVID-19 disproportionately
- Additionally, being unvaccinated, or not being up to date on COVID-19 vaccinations, also increases the risk of severe COVID-19 outcomes

https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html

INFLUENZA

RECOMMENDED ADULT IMMUNIZATION SCHEDULE FOR AGES 19 YEARS OR OLDER, UNITED STATES, 2024



https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf

CDC INFLUENZA IMMUNIZATION SCHEDULE

- Routine annual influenza vaccination of all persons aged ≥6 months who do not have contraindication.

https://www.cdc.gov/flu/professionals/vaccination/vax-summary.htm

USE OF TRIVALENT INFLUENZA VACCINES FOR THE 2024-2025 U.S. INFLUENZA SEASON

- Influenza virus strains for a trivalent vaccine composition for use in the U.S. were recommended on March 5, 2024 by the FDA VRBPAC
- Trivalent seasonal influenza vaccines include two influenza A viruses (H1N1 and H3N2) and one influenza B virus
- Influenza B viruses are classified into two lineages: B/Yamagata and B/Victoria
  - Evidence indicates that the B/Yamagata lineage virus no longer poses a public health threat
    - There have been no confirmed detections of circulating B/Yamagata lineage viruses worldwide after March 2020

https://www.fda.gov/vaccines-blood-biologics/lot-release/use-trivalent-influenza-vaccines-2024-2025-us-influenza-season

INFLUENZA VACCINE PRODUCTS BY AGE

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 (ccIIV4)		Flucelvax Quadrivalent				
	Adjuvanted inactivated (aIIV4)						Fluad Quadrivalent
	High-dose inactivated (HD-IIV4)						Fluzone High-Dose Quadrivalent
RIV4	Recombinant (RIV4)				Flublok Quadrivalent		
LAIV4	Live attenuated (LAIV4)			FluMist Quadrivalent			

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*

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/03-influenza-grohskopf-508.pdf

EGG ALLERGY

- People with egg allergy may receive any vaccine (egg-based or non-egg-based) that is otherwise appropriate for their age and health status
- Beginning with the 2023-2024 season, additional safety measures are no longer recommended for influenza vaccination of egg-allergic persons beyond those recommended for receipt of any vaccine, regardless of the severity of previous reaction to egg
- Contraindications still exist for previous allergic reaction to vaccine

https://www.cdc.gov/flu/professionals/vaccination/vax-summary.htm

PREFERENTIAL RECOMMENDATION FOR PEOPLE OVER THE AGE OF 65

Fluzone HD-IIV4	Flublok RIV4	Fluad aIIV4
• High dose • Four times the antigen	• Recombinant • Three times the antigen	• Adjuvanted • Adjuvant-an ingredient that helps create a stronger immune response

https://www.cdc.gov/flu/professionals/vaccination/vax-summary.htm

IMMUNOCOMPROMISED PATIENTS

- ACIP recommends high-dose inactivated (HD-IIV3) and adjuvanted inactivated (aIIV3) influenza vaccines as acceptable options for influenza vaccination of solid organ transplant recipients aged 18 through 64 years who are on immunosuppressive medication regimens, without a preference over other age-appropriate IIV3s or RIV3.

https://www.cdc.gov/vaccines/schedules/hcp/imz/adult-schedule-addendum.html

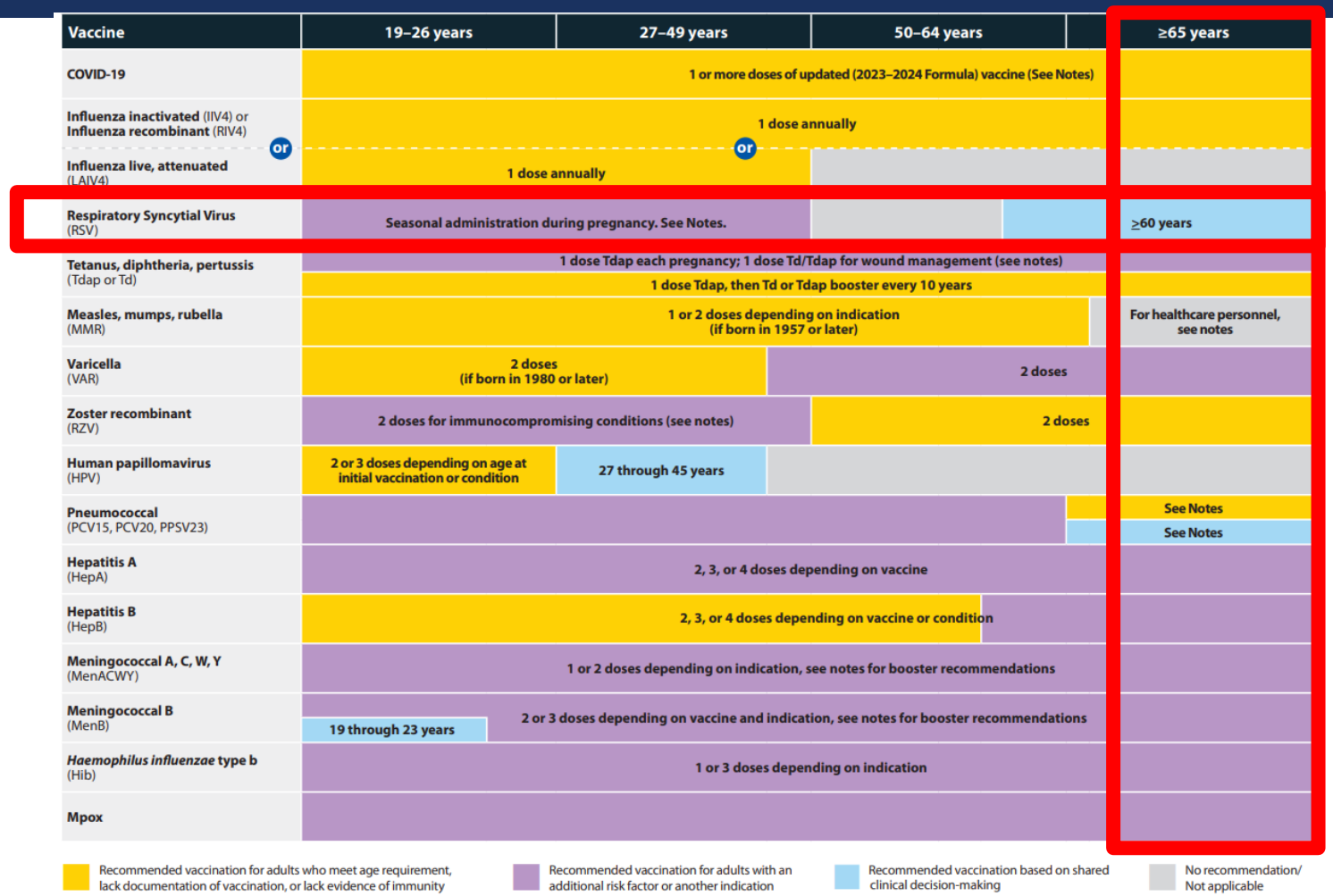
TIMING OF INFLUENZA VACCINES

- General Population: September or October
- Vaccination should continue after October and throughout the influenza season (Influenza viruses are circulating & Unexpired vaccine is available)
- Vaccination during July and August are not recommended for most groups
  - Considerations for July and August vaccination are noted for some children and pregnant persons

Grohskopf. https://www.cdc.gov/mmwr/volumes/72/rr/rr7202a1.htm

RESPIRATORY SYNCYTIAL VIRUS (RSV)

RECOMMENDED ADULT IMMUNIZATION SCHEDULE FOR AGES 19 YEARS OR OLDER, UNITED STATES, 2024



https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf

PREVIOUS RSV IMMUNIZATION SCHEDULE

- **Adults ages 60 and older: Two RSV vaccines** (Arexvy and Abrysvo) have been licensed by FDA and recommended by CDC for adults ages 60 and older, using shared clinical decision-making
- **Pregnant women: One RSV vaccine** (Pfizer Abrysvo) has been licensed and recommended during weeks 32 through 36 of pregnancy to protect infants

https://www.cdc.gov/rsv/about/prevention.html

UPDATES TO THE RSV IMMUNIZATION SCHEDULE

- ACIP recommends adults 75 years of age and older receive a single dose of RSV vaccine
- ACIP recommends adults 60–74 years of age and older who are at increased risk of severe RSV disease receive a single dose of RSV vaccine (kidney/heart/lung disease, obesity, reside in nursing home)

NOTES:

- These recommendations supplant the current recommendation that adults 60 years of age and older may receive RSV vaccination, using shared clinical decision-making. Adults 60–74 years of age who are not at increased risk of severe RSV disease are NOT recommended to receive RSV vaccination.
- RSV vaccination is currently recommended as a single lifetime dose only. Persons who have already received RSV vaccination are NOT recommended to receive another dose.

https://www.cdc.gov/vaccines/schedules/hcp/imz/adult-schedule-addendum.html

RSV VACCINE PRODUCT UPDATES

- New RSV Vaccine Receives FDA Approval, CDC Recommendation: Moderna's mRNA-platform-based mRESVIA®, the third RSV vaccine FDA-approved in the US, received CDC recommendation for use in adults aged ≥60 years of age
- FDA Expands Indication for GSK's RSV Vaccine Arexvy to adults aged 50-59 at increased risk for severe RSV disease; CDC Withholds Recommendation

https://www.cdc.gov/vaccines/vpd/rsv/index.html

RSV VACCINE TIMING

- Best time to get vaccinated is in the late summer or early fall — just before RSV usually starts to spread in the community

https://www.cdc.gov/rsv/about/prevention.html

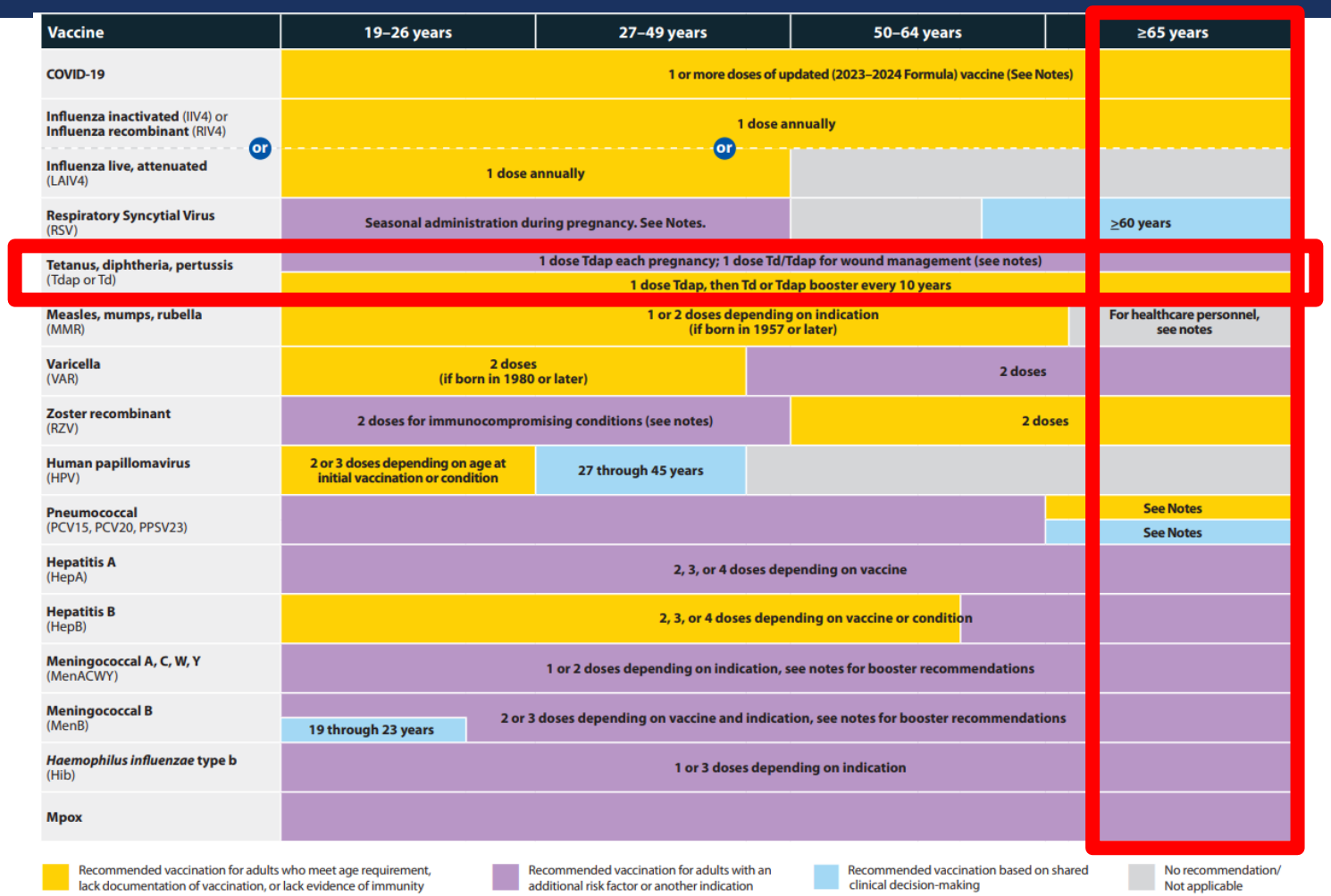
CDC ADDRESSES RSV VACCINE ADMINISTRATION ERRORS

- Administration errors for RSV vaccines are occurring in young children and pregnant people, most likely due to confusion over similar product names and differing indications
- The CDC released a bulletin describing the errors, which have been identified by VAERS through 1/17/24
  - 25 reports of administration errors in children younger than 24 months
  - 128 reports of errors in pregnant people
- Abrysvo (Pfizer) and Arexvy (GSK)
  - Neither of the two RSV vaccines is approved for use in infants or young children
  - Abrysvo is the only RSV vaccine recommended for pregnant people and Arexvy is not approved for use during pregnancy
- Nirsevimab (Beyfortus, Sanofi and AstraZeneca)
  - Human recombinant monoclonal antibody with activity against RSV
  - Only recommended for infants and some young children at increased risk for severe RSV disease.

https://emergency.cdc.gov/newsletters/coca/2024/012224.html

TETANUS, DIPHTHERIA, PERTUSSIS

RECOMMENDED ADULT IMMUNIZATION SCHEDULE FOR AGES 19 YEARS OR OLDER, UNITED STATES, 2024



https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf

TETANUS, DIPHTHERIA, PERTUSSIS VACCINATION SCHEDULE

- Adults who have never received Tdap should get a dose of Tdap
- Also, adults should receive a **booster dose of either Tdap or Td every 10 years**,
  - After 5 years in the case of a severe or dirty wound or burn
  - 1 dose with every pregnancy

https://www.cdc.gov/vaccines/hcp/vis/vis-statements/tdap.html

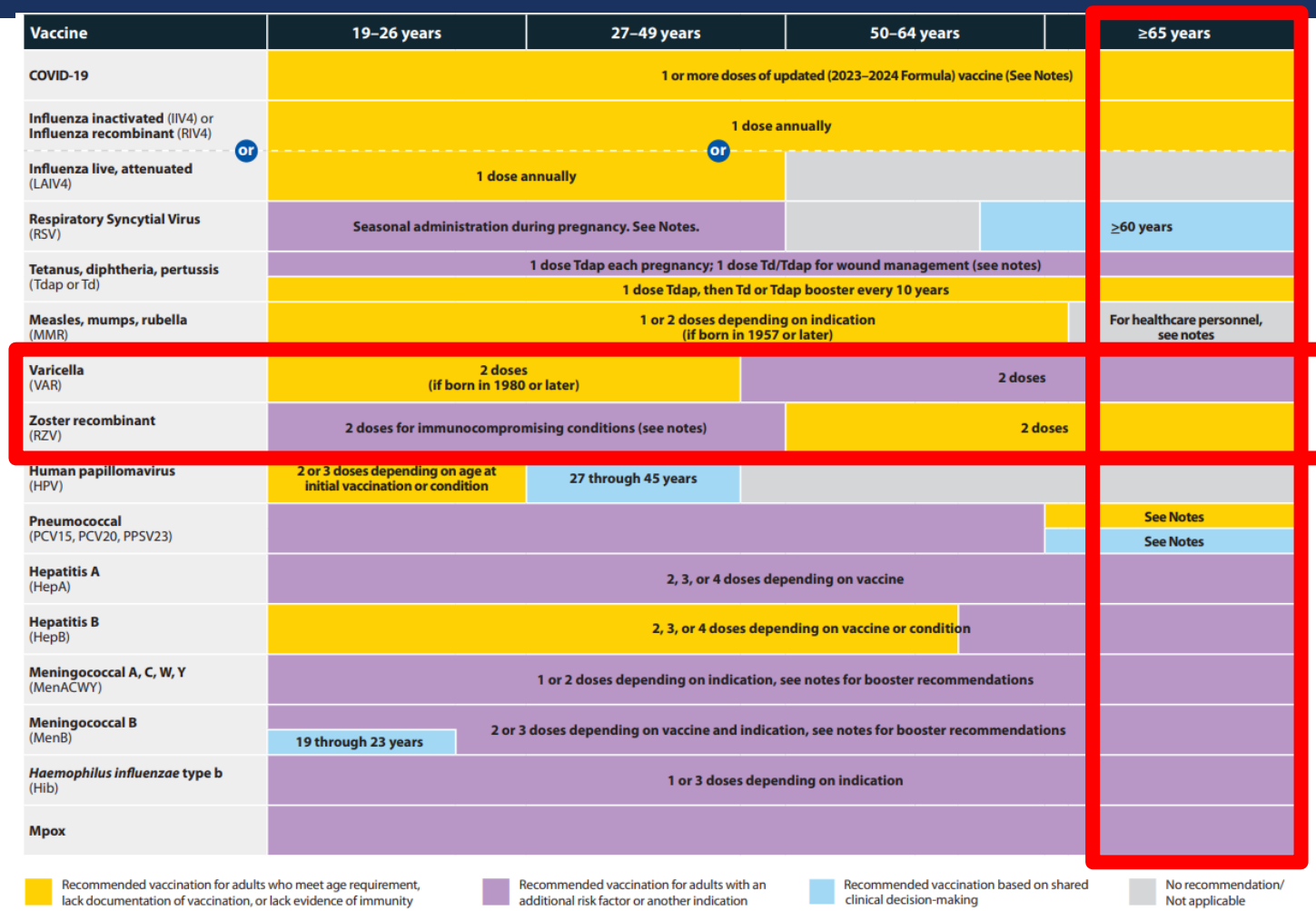
CONSTRAINED U.S. TD SUPPLY, 2024

- Historically, two tetanus and diphtheria (Td) vaccine products have been available for use in the United States:
  - TdVax™, manufactured by MassBiologics
  - Tenivac®, manufactured by Sanofi
- MassBiologics has discontinued production of TdVax™. Sanofi is taking steps to augment their available U.S. supply of Tenivac®. Despite these efforts, it's anticipated that the supply of Td vaccine in the U.S. market will be constrained during 2024.
- Temporary ordering controls are in place in the public and private sectors to help manage the gap in supply. Diphtheria, tetanus, and acellular pertussis (Tdap) vaccines are available without supply constraints at this time.
- The limited supply of Td vaccine needs to be preserved for those with a contraindication to receiving pertussis-containing vaccines.
  - Transition to use of Tdap vaccine in lieu of Td vaccine whenever possible while Td vaccine supplies are constrained.
  - Tdap vaccine is an acceptable alternative to Td vaccine, including when a tetanus booster is indicated for wound management, unless person has a specific contraindication to pertussis-containing vaccines.

https://www.cdc.gov/tetanus/clinicians.html

ZOSTER

RECOMMENDED ADULT IMMUNIZATION SCHEDULE FOR AGES 19 YEARS OR OLDER, UNITED STATES, 2024



https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf

VARICELLA VACCINE SCHEDULE

- Herpes zoster, also known as shingles, is caused by reactivation of varicella-zoster virus (VZV), the same virus that causes varicella (chickenpox)
- Adults only need to be immunized with a varicella vaccine if there is NO evidence of immunity to varicella
- Evidence of immunity
  - Born in U.S. before 1980
  - Documentation of receipt of 2 doses of varicella vaccine
  - Documented diagnosis of varicella or herpes zoster by a health care professional
  - Laboratory evidence of immunity

https://www.cdc.gov/vaccines/vpd/shingles/hcp/shingrix/recommendations.html

HERPES ZOSTER VACCINE FORMULATIONS

- Shingrix (Recombinant Zoster Vaccine)
- Zostavax (Zoster Vaccine Live) – Removed from market November 2020

https://www.cdc.gov/vaccines/vpd/varicella/hcp/index.html

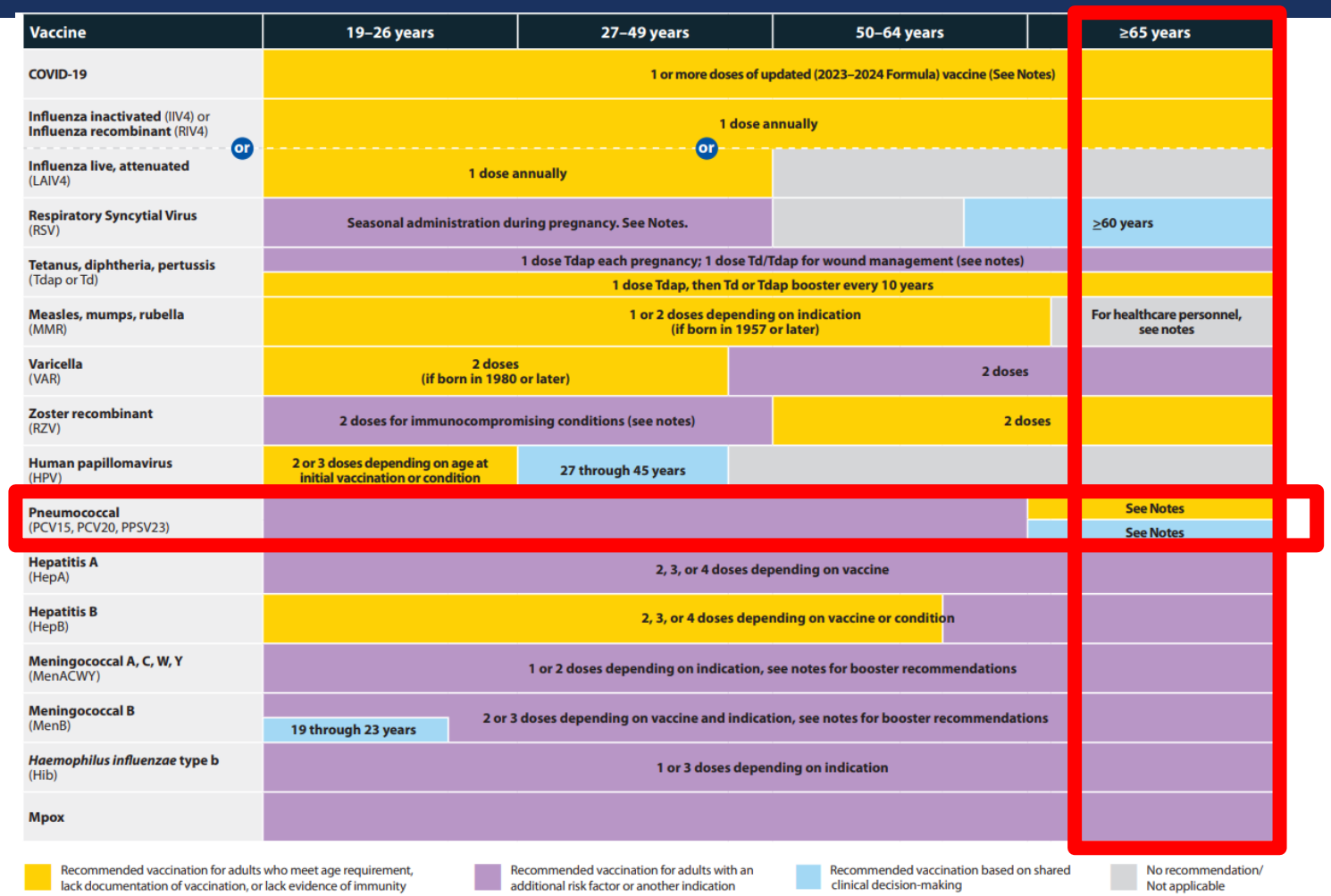
HERPES ZOSTER VACCINATION SCHEDULE

- CDC recommends two doses of Shingrix (recombinant zoster vaccine) separated by 2-6 months for the prevention of herpes zoster and related complications for immunocompetent adults aged 50 years and older:
  - Whether or not they report a prior episode of herpes zoster.
  - Whether or not they report a prior dose of Zostavax, a shingles vaccine that is no longer available for use in the United States.
  - It is not necessary to screen, either verbally or by laboratory serology, for evidence of prior varicella.
- CDC recommends two doses of RZV for the prevention of shingles and related complications in adults aged ≥19 years who are or will be immunodeficient or immunosuppressed because of disease or therapy.

https://www.cdc.gov/vaccines/vpd/shingles/hcp/shingrix/recommendations.html

PNEUMOCOCCAL

RECOMMENDED ADULT IMMUNIZATION SCHEDULE FOR AGES 19 YEARS OR OLDER, UNITED STATES, 2024



https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf

PNEUMOCOCCAL VACCINE HISTORY

1977	• First Pneumococcal polysaccharide vaccine licensed for use in US
1983	• PPSV23 licensed
2000	• PCV7 licensed (First conjugate vaccine)
2010	• PCV13 licensed
2012	• PCV13 for adults w/ immunocompromising conditions in addition to PPSV23
2014	• PCV 13 for all adults over 65 years in addition to PPSV 23
2021	• PCV 15 & PCV 20 licensed and recommended for adults
2024	• PCV 21 (Capvaxive™) licensed and recommended for adults

https://www.cdc.gov/vaccines/pubs/pinkbook/pneumo.html
https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/pneumo.html
https://www.cdc.gov/mmwr/volumes/72/rr/rr7203a1.htm

ADULT PNEUMOCOCCAL VACCINE SEROTYPE COVERAGE

	1	3	4	5	6A	6B	7F	9V	14	18C	19A	19F	23F	22F	33F	8	10A	11A	12F	15B	2	9N	17F	20	15A	15C	16F	23A	23B	24F	31	35B
PCV15																																
PCV20																																
PPSV23																																
PCV21																																

Loehr. ACIP Meeting. June 2024

UPDATED PNEUMOCOCCAL VACCINATION RECOMMENDATION

- ACIP recommends PCV21 as an option for adults aged ≥19 years who currently have a recommendation to receive a dose of PCV.

https://www.cdc.gov/vaccines/schedules/hcp/imz/adult-schedule-addendum.html

Adults ≥65 years old
Complete pneumococcal vaccine schedules

Prior vaccines	Option A	Option B
None*	**PCV20**	**PCV15** → ≥1 year† → **PPSV23**
PPSV23 only at any age	≥1 year → **PCV20**	≥1 year → **PCV15**
PCV13 only at any age	≥1 year → **PCV20**	≥1 year† → **PPSV23**
PCV13 at any age & **PPSV23** at <65 yrs	≥5 years → **PCV20**	≥5 years§ → **PPSV23**

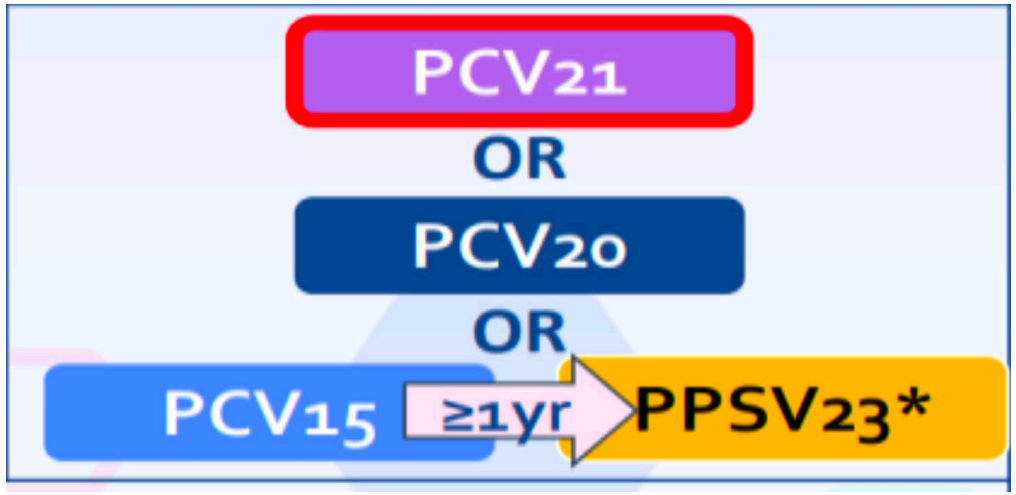
* Also applies to people who received PCV7 at any age and no other pneumococcal vaccines
† Consider minimum interval (8 weeks) for adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak (CSF) leak
§ For adults with an immunocompromising condition, cochlear implant, or CSF leak, the minimum interval for PPSV23 is ≥8 weeks since last PCV13 dose and ≥5 years since last PPSV23 dose; for others, the minimum interval for PPSV23 is ≥1 year since last PCV13 dose and ≥5 years since last PPSV23 dose

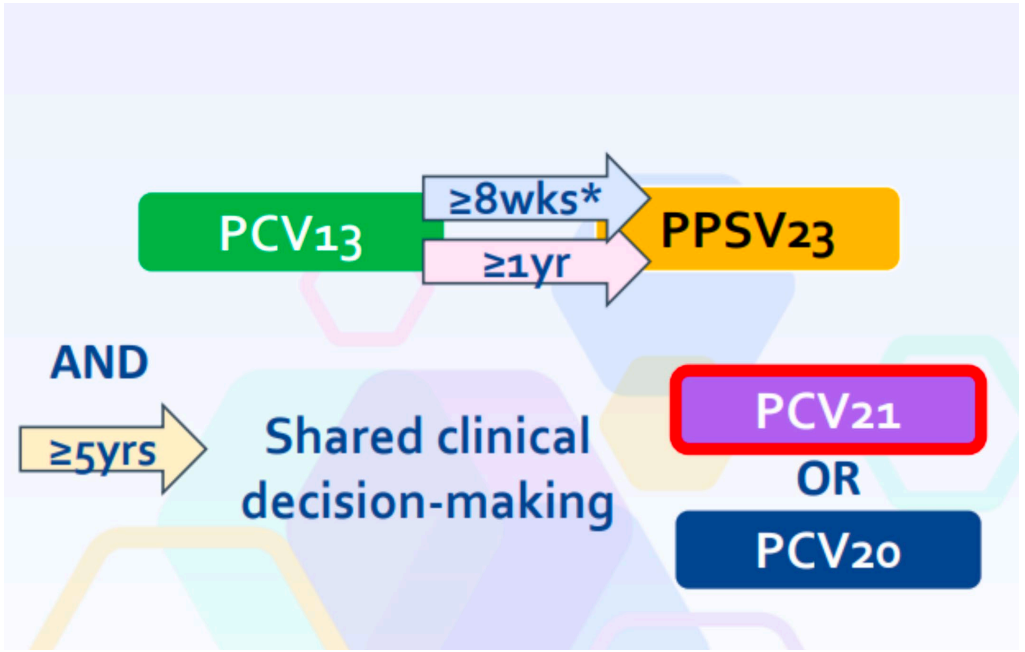
https://www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf

Shared clinical decision-making for those who already completed the series with PCV13 and PPSV23

Prior vaccines	Shared clinical decision-making option		
Complete series: **PCV13** at any age & **PPSV23** at ≥65 yrs	≥5 years	**PCV20**	Together, with the patient, vaccine providers **may choose** to administer PCV20 to adults ≥65 years old who have already received PCV13 (but not PCV15 or PCV20) at any age and PPSV23 at or after the age of 65 years old.

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



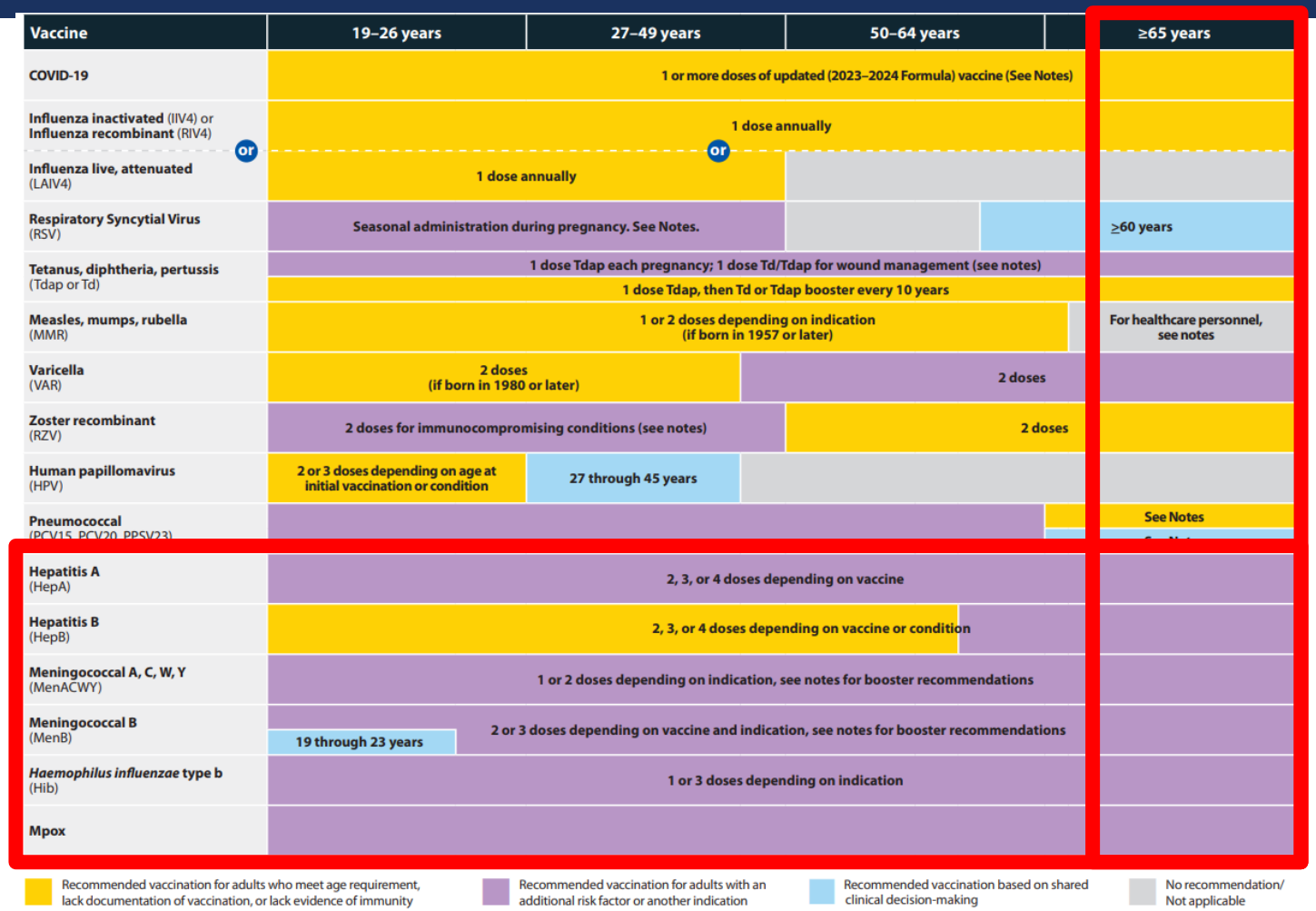


Kobayashi. ACIP Meeting. June 2024.

HEPATITIS A
HEPATITIS B
MENINGOCOCCAL
HAEMOPHILUS INFLUENZAE TYPE B VACCINATION
MPOX

RECOMMENDED VACCINATION FOR ADULTS WITH AN ADDITIONAL RISK FACTOR OR ANOTHER INDICATION

RECOMMENDED ADULT IMMUNIZATION SCHEDULE FOR AGES 19 YEARS OR OLDER, UNITED STATES, 2024



https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf

HEPATITIS A- ADULT VACCINATION SCHEDULE

- Any person not fully vaccinated, and requests vaccination – receive Hep A vaccine series
- Any person not fully vaccinated and is at risk of hepatitis A infection should receive a Hep A vaccine series

HEPATITIS A RISK FACTORS

- Men who have sex with men
- Injection or non-injection drug use
- Persons experiencing homelessness
- Work with hepatitis A virus
- Close contact with an international adoptee
- Traveling to an area where there is high or intermediate endemic hepatis A
- Settings for exposure (heath care settings for injection or non-injection drug users or group homes, nonresidential day care facilities for developmentally disabled persons)
- Certain Chronic conditions
  - Chronic liver disease
  - Hepatitis B infection
  - Hep C infection
  - HIV infection

https://www.cdc.gov/vaccines/schedules/hcp/imz/adult-schedule-notes.html

HEPATITIS B-ADULT VACCINATION SCHEDULE

- All adults 19-59 years should receive a hepatitis B vaccine series
- Persons aged 60 years & older WITH known risk factors for hepatitis B virus infection SHOULD complete a HepB vaccine series
- Persons aged 60 years & older WITHOUT known risk factors for hepatitis B virus infection MAY complete a HepB vaccine series
- Shared clinical decision making: hepatitis B vaccination for adults aged 60 years and older with diabetes mellitus

https://www.cdc.gov/vaccines/schedules/hcp/imz/adult-schedule-notes.html

HEPATITIS B RISK FACTORS

- Percutaneous or mucosal risk of exposure to blood
- Current or recent injection drug use
- At risk by sexual contact
- Living with someone who has active hepatitis B infection
- Incarceration
- Traveling outside the US to an area where hepatitis B is common
- Certain Chronic conditions
  - End stage renal disease or on dialysis
  - Chronic liver disease
  - Hep C infection
  - HIV infection

https://www.cdc.gov/vaccines/schedules/hcp/imz/adult-schedule-notes.html

MENINGOCOCCAL VACCINES- ADULT IMMUNIZATION SCHEDULE

- Not routinely recommended for adult patients
- Special situations:
  - Anatomical or functional asplenia (including sickle cell disease), HIV infection, complement component deficiency or taking complement component inhibitor
  - Travel in countries with hyperendemic or epidemic meningococcal disease or microbiologist routinely exposed to Neisseria meningitidis
  - College students or military recruits

https://www.cdc.gov/vaccines/schedules/hcp/imz/adult-schedule-notes.html

HAEMOPHILUS INFLUENZAE TYPE B VACCINATION SCHEDULE

- Not routinely recommended for adult patients
- Special situations:
  - **Anatomical or functional asplenia (including sickle cell disease)**
  - **Hematopoietic stem cell transplant (HSCT)**

https://www.cdc.gov/vaccines/schedules/hcp/imz/adult-schedule-notes.html

MONKEYPOX VACCINE- ADULT IMMUNIZATION SCHEDULE

- ACIP recommends vaccination with the 2-dose mpox vaccine series for persons aged 18 years and older at risk for monkeypox

https://www.cdc.gov/vaccines/schedules/hcp/imz/adult-schedule-notes.html

MONKEYPOX RISK FACTORS

- Gay, bisexual, and other men who have sex with men, transgender or nonbinary people who in the past 6 months have had one of the following:
  - A new diagnosis of more than one sexually transmitted disease
  - More than one sex partner
  - Sex at a commercial sex venue
  - Sex in association with a large public event in a geographic area where mpox transmission is occurring
- Sexual partners of persons with the risks described in above
- Persons who anticipate experiencing any of the above
- Work in a setting where you may be exposed to monkeypox (such as a laboratory working on orthopoxviruses)

https://www.cdc.gov/vaccines/schedules/hcp/imz/adult-schedule-notes.html

VACCINE ACTION PLAN

- Seasonality
  - Influenza, RSV
- Severity/Lethality
  - Pneumococcal before Zoster
- Incidence
  - Zoster before Tdap or Hep B
- Outbreak setting or personal situation
  - COVID-19, Mpox
- Multidose series
  - Zoster, Hep B

https://www.pharmacist.com/Education/Adult-Vaccination-Needs

My Vaccine Action Plan

Patient Name	Date
Patient Email	Patient Telephone
Vaccine Provider	Provider Contact

About me:	Personal Preferences:	Vaccines I need in next 12 months (check all that apply):
Age_____ DOB_____	❑ More shots per visit, fewer visits	❑ COVID-19
Health conditions	❑ Fewer shots per visit, more visits	❑ Hepatitis A ____ doses needed
	Sooner vaccinated = sooner protected.	❑ Hepatitis B ____ doses needed
	Multiple shots per visit recommended.	❑ Human papillomavirus (HPV)
Occupation		❑ Influenza (flu, annual)
Travel plans	**My priorities:**	❑ Measles-mumps-rubella (MMR)
Life events		❑ Meningococcal ACWY
Other	**Notes:**	❑ Meningococcal B
		❑ Mpox
		❑ Other _____

❑ Pneumococcal_____
❑ Polio
❑ RSV (respiratory syncytial virus)
❑ Tetanus-diphtheria-pertussis (Tdap) or (Td) [circle]
❑ Varicella (chickenpox)
❑ Zoster (shingles)
❑ Travel _____
❑ Other _____
❑ Other _____

My Vaccine Action Plan *(complete with your vaccine provider)*

Jan_____	Feb_____	Mar_____	Apr_____	May_____	Jun_____
Jul_____	Aug_____	Sep_____	Oct_____	Nov_____	Dec_____
Jan_____	Feb_____	Mar_____	Apr_____	May_____	Jun_____

1. Enter year for this month and following months.
2. Fill in any upcoming appointments already scheduled.
3. Add vaccines based on recommendations personalized for you. Consider vaccine series not yet complete as well as seasonal vaccines and other vaccines.
4. Schedule appointments to fill these vaccine needs. Ask for reminders to come back for appointments.

CDC VACCINE SCREENING APPS

THE END

QUESTIONS

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