Vaccines: Today & Tomorrow

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Key Players in U.S. Vaccine Ecosystem

- Pharma
- FDA
- HHS/CDC/ACIP
- Foundations, Funders, Researchers

- Advocacy Groups
- Public Health and Associations
- Payers
- Global influences

National Vaccine Plan 2021-25 Goals

- Develop New and Improved Vaccines
- Enhance Vaccine Safety System
- Support Communication to Inform Enhanced Vaccine Decision Making
- Ensure a Stable Supply of, Access to, & Better Use of Recommended Vaccines in the United States
- Increase Global Prevention of Death and Disease through Safe and Effective Vaccination
- The National Strategic Plan for Vaccines 2021-2025 | HHS.gov

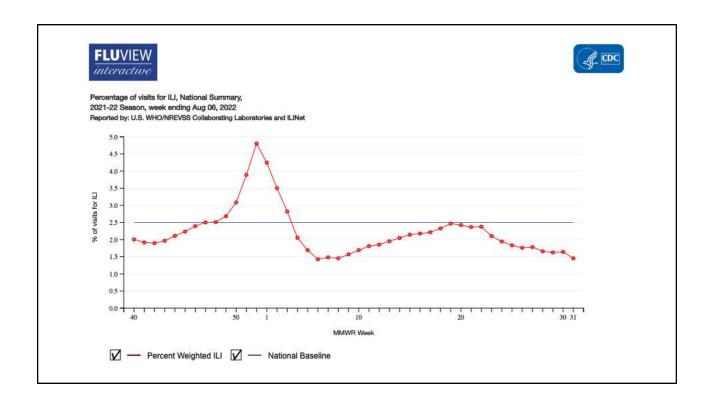
Dr. Georgina Peacock

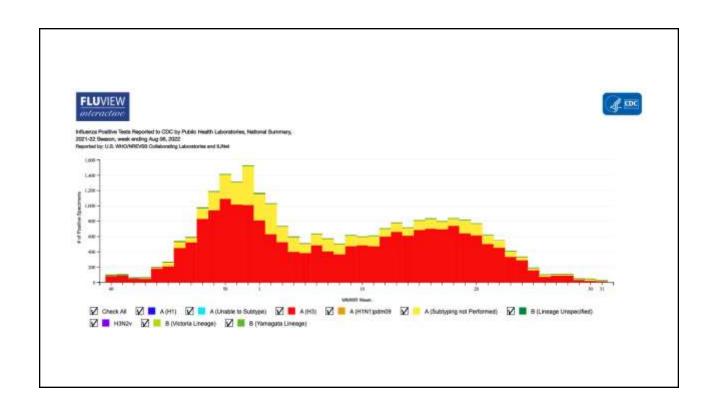
Vaccine Priority #1 for the CDC

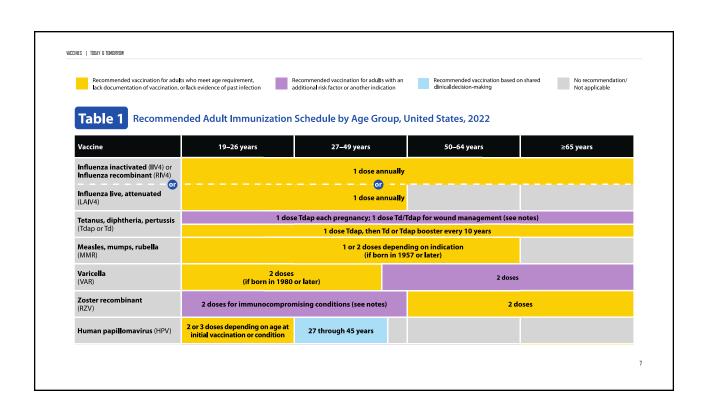
CLOSE vaccine gaps across all ages

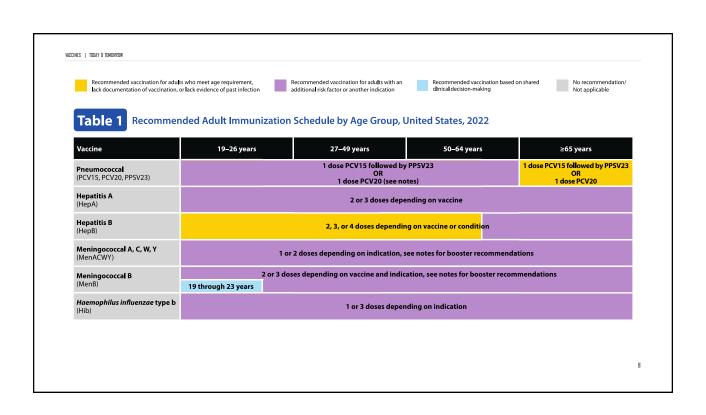
• Co-Administration with COVID vaccine as needed for catch up

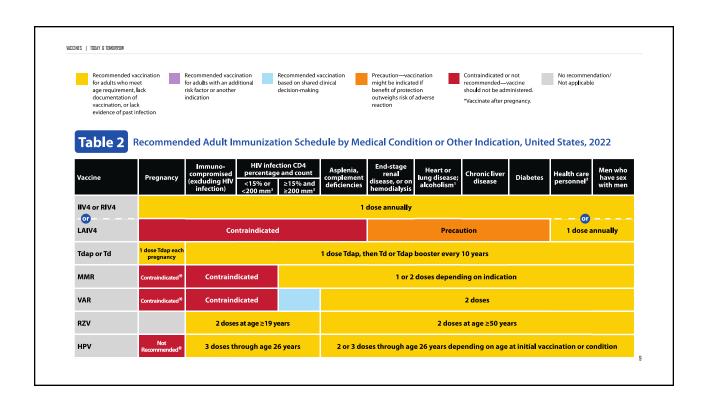


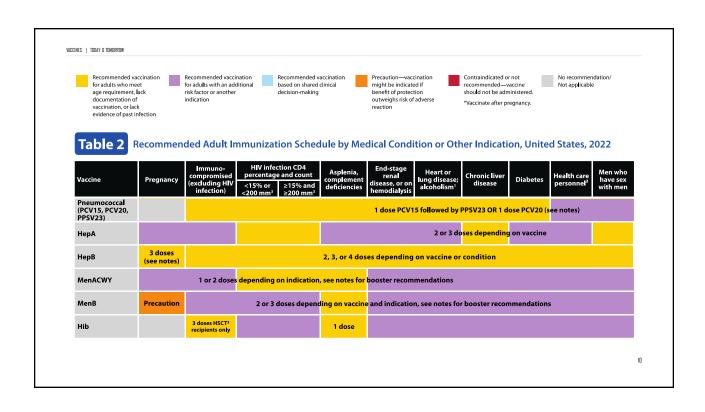












Adult Schedule Updates

- Hepatitis B vaccine universal use ages 19-59
- Pneumococcal vaccines
 - Age 65+: PCV20 OR PCVI5 w/ PPSV23 to follow
 - Ages 19-64 risk-based usage
- Recombinant zoster vaccine (RZV)
 - Added 19-49 years if immunocompromised
- COVID-19 vaccine: links in schedule for most UTD recs

Many US Adults Are Not Fully Protected against Hepatitis B - National Foundation for Infectious Diseases (nfid.org)

<u>Use of RZV in Immunocompromised Adults Aged >19 Years (medscape.com)</u>

Other Adult Changes

- Menquadfi replaces Menactra (Men ACWY) from Sanofi, broader age indication (2yrs+), different adjuvant (TT vs D)
- PrevHevBrio New Adult Hep B recombinant vaccine. In use in Israel x 20 years, may give better immune response in adults w/comorbidities.
- Meningococcal B Shared Decision Making (SDM) Ages 16-23
- HPV 9 SDM ages 27-45

<u>Our Pipeline: A Broad Spectrum of Vaccines & Immunotherapeutics | VBI Vaccines Inc.</u>

Men-B

Consider discussing Men B vaccination with patients 16-23 years of age who are not at increased risk for meningococcal disease:



-MenB vaccine is not routinely recommended for all adolescents in this age group.

•The vaccine series provides short-term protection against most strains of serogroup B meningococcal bacteria circulating in the United States.





Serogroup B meningococcal disease is an uncommon but deadly disease. In recent years, between 20 and 50 cases occurred in 16 to 23 year olds in the United States each year.

- A low risk of exposure or infection does not mean a person cannot get a MenB vaccine. It is just one potentially important consideration in shared clinical
- decision-making.
 -College students are at increased risk, especially those who are freshmen, attend a four-year university, live in on-campus housing, or participate in sororities and fraternities.
- Serogroup B vaccines are safe and effective, but only offer short-term protection (1 to 2 years) to those who get vaccinated.

If you vaccinate:



•Since these patients are not at increased risk of serogroup B disease, administer:

- -2-dose series of MenB-4C at least 1 month apart, or

- -2-dose series of MenB-FHbp at 0, 6 months

 -MenB-4C and MenB-FHbp are not interchangeable

 -MenB vaccines are safe and effective for this population unless a patient -Had a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component
- Is pregnant; vaccine should be delayed unless the patient is at increased risk and the benefits of vaccination outweigh the potential risks

HPV

for Adults Aged
27-45 Years

HPV vaccination does not need to be discussed with most adults in this age group.

If you do decide to discuss HPV vaccination with an adult patient:

Remember:



- Most HPV infections clear on their own within a year or two, but persistent infections can lead to development of precancers or cancers, usually after several decades.
- HPV vaccination is not routinely recommended for adults 27-45 years of age.
- HPV vaccine effectiveness is highest in people who have never had sex.
- HPV vaccination prevents new HPV infection, it does not treat existing HPV infection or disease.
- Most adults who have had sex have been exposed to HPV before.
- HPV vaccine effectiveness might be low among people with more risk factors for HPV, such as having had sex with more than one person or having certain immunocompromising conditions.

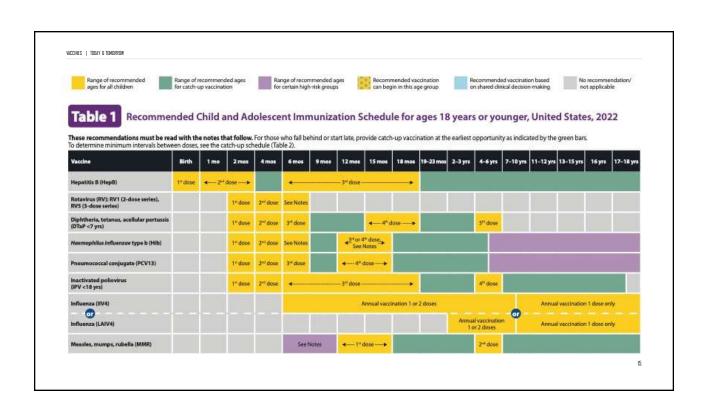
Consider:

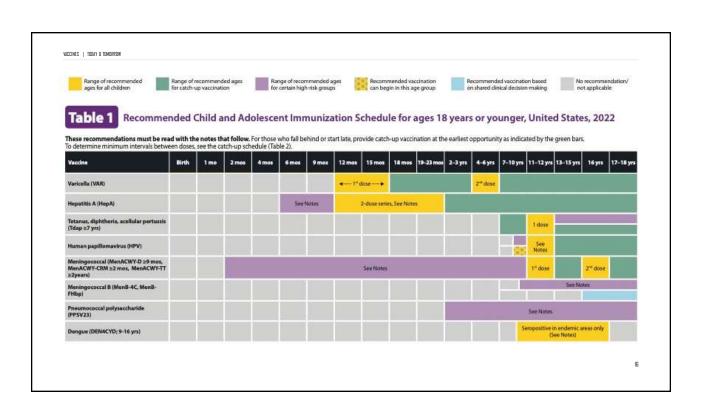


- At any age, having a new sex partner is a risk factor for getting a new HPV infection. However, this is only one possible consideration for SCDM.
- Adults with more HPV risk factors (for example, multiple previous sex partners or certain immunocompromising conditions) might have been infected with HPV in the past, so might have a lower chance of getting a new HPV infection in the future.
- Adults with fewer HPV risk factors (for example, few or no previous sex partners) might not have been infected with HPV in the past, so might have a higher chance of getting a new HPV infection from a new sex partner in the future.



- If you and your previously unvaccinated adult patient decide to initiate HPV vaccination, offer a 3-dose series of HPV vaccine at 0, 2, and 6 months.
- If your patient is pregnant, delay HPV vaccination until after pregnancy.
- HPV vaccination is safe, unless a patient had a severe allergic reaction after a previous dose or to a vaccine component.





Pediatric Schedule Updates

- CATCH UP ALL DOSES ASAP
- Dengue for endemic areas (Puerto Rico, USVI, American Samoa, Marshall Is.), 9-16 years
- Vaxneuvance (PCV I5) ages 6 weeks +, can complete series
- Vaxelis (DTaP, Inactivated Poliovirus, Haemophilus b Conjugate & Hepatitis B Vaccine) added to HIB schedule options
- Menquadfi replaces Menactra (Men ACWY)
- Men B: Adolescents not at increased risk, age 16-23 years (preferred age 16-18 years) based on SDM
 - Bexsero®: 2-dose series at least 1 month apart
 - Trumenba®: 2-dose series at least 6 months apart; if dose 2 is administered earlier than 6 months, administer a 3rd dose
 at least 4 months after dose 2

2021: Haemophilus Influenzae type b-Containing Vaccines—Catch-up Guidance for Children 4 months through 4 years of Age (cdc.gov)

Table 1. Immunization Schedule for Children 6 Months through 17 Years of Age

Туре	Product*	Recipient Age	For Most People		Those Who ARE Moderately or Severely Immunocompromised	
			Doses	Interval Between Doses ^{1‡}	Doses	Interval Between Doses ¹¹
	Moderna	6 months through 5 years	Total doses: 2 doses		Total doses: 3 doses	
	(Blue vial cap with magenta-		Dose 1 to 2	At least 4–8 weeks*	Dose 1 to 2	At least 4 weeks
	bordered label)				Dose 2 to 3	At least 4 weeks
	Moderna	6 through 11 years	Total doses: 2 doses		Total doses: 3 doses	
	(Blue vial cap with purple-		Dose 1 to 2	At least 4–8 weeks [‡]	Dose 1 to 2	At least 4 weeks
	bordered label				Dose 2 to 3	At least 4 weeks
	Moderna	cap through	Total doses: 2 doses		Total doses: 3 doses	
	(Red vial cap with blue-		Daniel In 2		Dose 1 to 2	At least 4 weeks
mRNA vaccine	bordered label)		Dose 1 to 2 At least 4–8 weeks [‡]	Dose 2 to 3	At least 4 weeks	
	Pfizer-BioNTech (Maroon vial cap with maroon- bordered label)	6 months through 4 years	Total number: 3 doses		Total number: 3 doses	
			Dose 1 to 2	At least 3–8 weeks*	Dose 1 to 2	At least 3 weeks
			Doses 2 and 3	At least 8 weeks	Dose 2 to 3	At least 8 weeks

В

Table 1. Immunization Schedule for Children 6 Months through 17 Years of Age

Туре	Product*	Recipient Age	For Most People		Those Who ARE Moderately or Severely Immunocompromised	
			Doses	Interval Between Doses ^{†‡}	Doses	Interval Between Doses ¹¹
	Pfizer-BioNTech (Orange vial cap with orange- bordered label)	5 through 11 years	Total number: 3 doses		Total number: 4 doses	
			Dose 1 to 2	At least 3-8 weeks [‡]	Dose 1 to 2	At least 3 weeks
				At least 5 months	Dose 2 to 3	At least 4 weeks
			Dose 2 to 3		Dose 3 to 4	At least 3 months
	Pfizer- BioNTech (Purple vial cap with a purple- bordered label or gray vial cap with gray- bordered label)	through ap 17 years	Total number: 3 doses		Total number: 5 doses	
			Dose 1 to 2	At least 3-8 weeks*	Dose 1 to 2	At least 3 weeks
					Dose 2 to 3	At least 4 weeks
			Dose 2 to 3	At least 5 months	Dose 3 to 4	At least 3 months
					Dose 4 to 5	At least 4 months

Table 2. Immunization Schedule for Persons 18 Years of Age

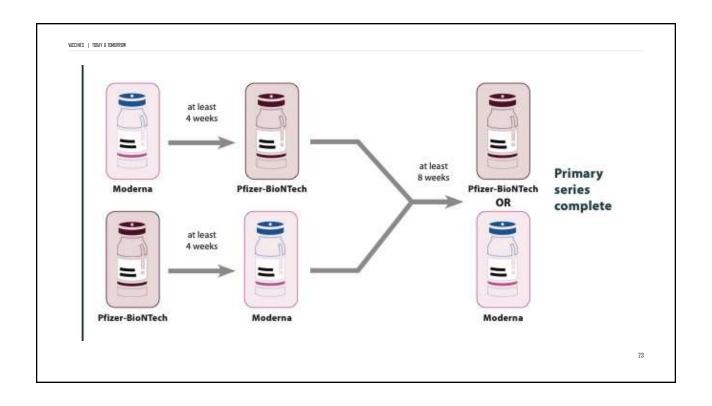
Туре	Product*	Recipient Age	For Most People		Those Who ARE Moderately or Severely Immunocompromised	
			Doses	Interval Between Doses**	Doses	Interval Between Doses**
	Moderna	18 years and older	Total number: 3 or 4 doses		Total number: 5 doses	
			Dose 1 to 2	At least 4–8 weeks*	Dose 1 to 2	At least 4 weeks
	(Red vial cap with a blue- bordered label)		Dose 2 to 3 ⁵	At least 5 months	Dose 2 to 3	At least 4 weeks
	label)		Dose 3 to 4 ⁶	At least 4 months for persons ages 50 years and older	Dose 3 to 4 ⁵	At least 3 months
RNA			Dose 3 to 4°		Dose 4 to 5 ⁵	At least 4 months

Table 2. Immunization Schedule for Persons 18 Years of Age

Туре	Product*	Recipient Age	For Most People		Those Who ARE Moderately or Severely Immunocompromised	
			Doses	Interval Between Doses**	Doses	Interval Between Doses**
vaccine	Pfizer- BioNTech (Purple vial cap with a purple- bordered label or gray vial cap with gray- bordered label)	18 years and older	Total number: 3 or 4 doses		Total number: 5 doses	
			Dose 1 to 2	At least 3-8 weeks*	Dose 1 to 2	At least 3 weeks
			Dose 2 to 3	At least 5 months ⁶	Dose 2 to 3	At least 4 weeks
			Dose 3 to 4 At least 4 months for persons ages 50 years and older ⁶	Dose 3 to 4 ⁵	At least 3 months	
				Dose 4 to 5 ⁹	At least 4 months	
Protein subunit vaccine	Novavax	18 years and older	Total number: 2 doses‡		Total number: 2 doses	
			Dose 1 to 2	At least 3–8 weeks†	Dose 1 to 2	At least 3 weeks

Table 2. Immunization Schedule for Persons 18 Years of Age

Туре	Product*	Recipient Age	For Most People		Those Who ARE Moderately or Severely Immunocompromised	
			Doses	Interval Between Doses**	Doses	Interval Between Doses*
Adenovius vector vaccine	Janssen*	18 years and older	Total number: 2 or 3 doses		Total number: 4 doses	
			Dose 1 to 2	At least 8 weeks	Dose 1 to 2	At least 4 weeks (mRNA vaccine)*
			********	At least 4 months for persons ages 50 years and older (mRNA vaccine)**	Dose 2 to 3	At least 8 weeks*
			Dose 2 to 3		Dose 3 to 4	At least 4 months (mRNA vaccine)*



Product*	Age Indications†	Diluent	Dose/Injection Amount		
Type: mRNA vaccine					
Moderna (Blue vial cap with magenta-bordered label)	6 months through 5 years	NONE	Any dose in the primary series. Booster doses are not recommended for this age group.	25 μg/ 0.25 mL	
Moderna (Blue vial cap with purple-bordered label	6 through 11 years	NONE	Any dose in the primary series. Booster doses are not authorized for children, ages 6 through 11 years, who received a Moderna primary series.		
	18 years and older NONE		Booster dose only.	50 µg/0.5 mL	
Moderna (Red vial cap with	12 years and older	NONE	Any dose in the primary series. Booster doses are not authorized for adolescents, ages 12 through 17 years, who received a Modema primary series.	100 μg/ 0.5 ml	
blue- bordered label)	40.000	NONE	Any dose in the primary series.	100 μg/ 0.5 ml	
	18 years and older	NONE	Booster dose	50 μg/ 0.25 mL	
Pfizer-BioNTech (Maroon vial cap with maroon-bordered label)	6 months through 4 years	2.2 mL 0.9% sodium chloride (normal saline, preservative-free)	Any dose in the primary series. Booster doses are not recommended for this age group.	3 μg/0.2 mL	
Pfizer-BioNTech (Orange vial cap with orange-bordered label)	5 through 11 years	1.3 mL 0.9% sodium chloride (normal saline, preservative-free)	Any dose in the primary series and booster doses.	10 μg/0.2 mL	

VACCINES I TODAY & TOMORROW Table 3. COVID-19 Vaccine Products Summary Age Indications† Product* Diluent **Dose/Injection Amount** Type: mRNA vaccine Pfizer-BioNTech 1.8 mL 0.9% sodium chloride (normal saline, preservative-free) Any dose in the primary series and booster doses. (Purple vial cap with a purple-bordered label) 12 years and older 30 µg/0.3 mL Pfizer-BioNTech (Gray vial cap with a gray-bordered label) Any dose in the primary series and NONE 12 years and older 30 µg/0.3 mL booster doses. Age Indications Diluent Product Dose/Injection Amount Type: Protein sub unit vaccine Any dose in the primary series. Persons who received a Novavax COVID-19 Vaccine primary series are not eligible 5 μg rS and 50 μg of Matrix-M™ adjuvant/0.5 mL Novavax (Royal blue cap) 18 years and older NONE for booster doses (any product). Age Indications Product Diluent Dose/Injection Amount Type: Viral vector vaccine 5×1010 viral Janssen* NONE 18 years and older Primary and 1st booster dose. (Blue Cap) particles/0.5 mL

25

Monkeypox Vaccines

2 Vaccines

- Jynneos approved 2019, being shipped now to select sites, demand vastly outstrips supply, likely to get
 1st dose only for MSM and other hi risk groups (2 dose series, 4 wks apart), 786K doses to be shipped
- ACAM 2000 (older vaccine, smallpox vax), in greater supply but variolation technique required, NOT for
 use with Immunocompromised, Pregnancy, Eczema
- Both PrEP (best option) and PEP (before Sx start, best within 4 days of exposure, some efficacy up to 14 days))

Mankeypax (hhs.gav)

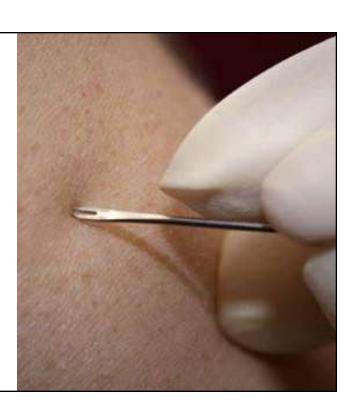
Considerations for Monkeypox Vaccination | Monkeypox | Poxvirus | CDC

Key Facts About Monkeypox Vaccine | FDA

There's Already a Vaccine For Monkeypox. Here's What We Know About it (cnet.com)

MACCINES I TODAY & TOMORPO

Variolation Technique





Future Developments

- Pan COVID vaccines spike proteins and more
- Universal Flu Vaccines
- Mucosal (nasal and gut administration) immunity
- More trials involving high risk populations
- Correlates of Protection markers (GMT/Antibody levels)

New COVID vaccines: here's the White House's plan | Popular Science (popsci.com)

Seroprotection rate, mean fold increase, seroconversion rate: which parameter adequately expresses seroresponse to influenza vaccination? - PubMed (nih.gov)

Universal Flu Vaccine Goals

- At least 75% effective
- Likely to target the stem (stable) rather than head (variable) of virus
- Protection lasting at least one year
- May be boosted by seasonal flu vaccines
- Suitable for all age groups
- Offers protection for all/most influenza strains

<u>Universal Influenza Vaccine Research | NIH: National Institute of Allergy and Infectious Diseases</u>

<u>Trial of potential universal flu vaccine opens at NIH Clinical Center</u> | National Institutes of Health (NIH)

Pipeline Vaccines

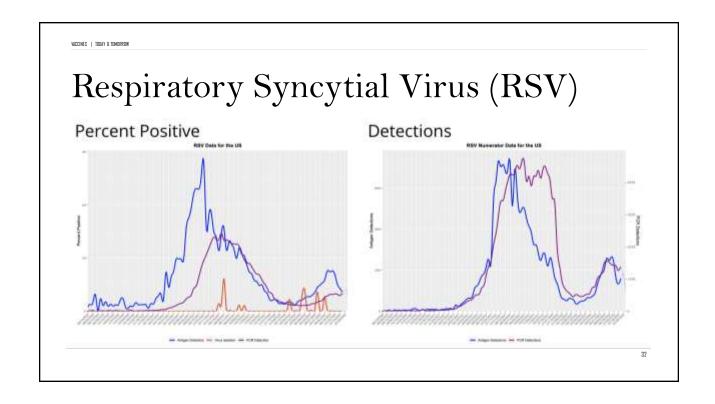
- CMV primary prevention and ? therapeutic options (glioblastoma),
- Multiple mRNA vaccines potential: HIV, Zika, Malaria, TB (+/- lipid coated nanoparticle)
- RSV Adults and <24 months likely
 - Late clinical trials underway, e.g. VANIR study enrolling age 60+ now (mRNA)
 - 4 vaccines based in 3 technologies (Protein subunits, Viral vector, mRNA)
 - Awareness campaigns already underway

CMV-DC Vaccine in Treating Patients with Newly Diagnosed or Recurrent Glioblastoma, Recurrent Malignant Glioma, or Recurrent Medulloblastoma (cancer.gov)

The Application and Future Potential of mRNA Vaccines < Yale School of Public Health

mRNA technology promises to revolutionize future vaccines and treatments for cancer, infectious diseases | AAMC

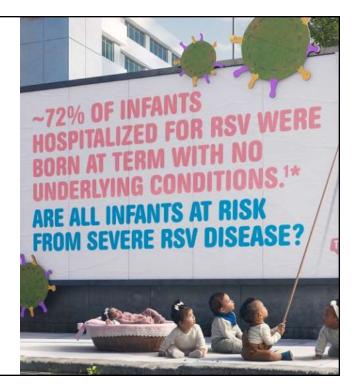
<u>Is There an RSV Vaccine, or Will One Be Developed Soon? - GoodRx</u>



VACCINES I TODAY & TOMODOO

Sanofi Pasteur "Rethink RSV" Launch

Pediatric dose:



10 June 2022 (Investor & Media)

GSK announces positive pivotal phase III data for its respiratory syncytial virus (RSV) vaccine candidate for older adults

Prefusion F Protein-Based Respiratory Syncytial Virus Immunization in Pregnancy PubMed (nih.gov)

Conclusions: RSVpreF vaccine elicited neutralizing antibody responses with efficient transplacental transfer and without evident safety concerns. (Funded by Pfizer; ClinicalTrials.gov number, NCT04032093).

NE.IM Anril 28 2022

Mosquirix

Key takeaways:

- In October 2021, the World Health Organization (WHO)
 recommended a malaria vaccine for children living in areas
 where malaria is common. This is the world's first malaria
 vaccine.
- The vaccine is called RTS,S (RTS,S/ASOI), but it's also known as Mosquirix.
- The vaccine is about 30% effective against severe sickness caused by one particular type of malaria parasite (P. falciparum).
- DNLY vaccine currently available, meets WHO guidance for minimum 75% effectiveness
- Manufactured by GSK, 3D years in development with PATH, UNICEF, Gates Foundation
- In 2019: 400,000 deaths worldwide, mostly children
- World Health Organization (WHD) Recommends Newly
 Approved Malaria Vaccine GoodRx

Malaria Vaccine

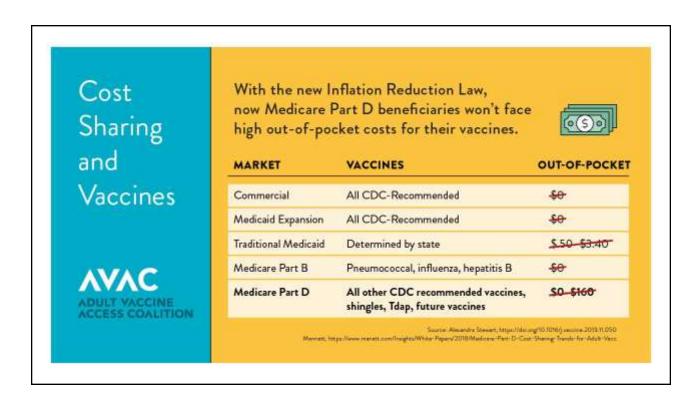
- Chemoprophylaxis Vaccination
- Phase 2 in Mali now
- Live sporozites plus either Pyrimethamine or Chloroquine
- mRNA vaccine offers another option

<u>Malaria vaccines provide strong and lasting immunity | National Institutes of</u> Health (NIH)



Proposals in 2022-23 White House Budget

- New VFA program for uninsured adults
- Move Medicare Part D vaccines to Part B: SIGNED INTO LAW



Favorite Resources

- Immunization Action Coalition (Immunize.org)
- Vaccinate Your Family (vaccinateyourfamily.org)
- National Foundation For Infectious Diseases (NFID.org)
- CDC Immunization Division (Vaccines and Immunizations | CDC)
- Vaccine Information Statements (VISs) | CDC
- Vaccine Adverse Events Reporting System (<u>Vaccine Adverse Event Reporting System (VAERS) | CDC</u>)
 - $\bullet \quad \text{V-SAFE (COVID only self report):} \underline{\text{V-safe After Vaccination Health Checker} \mid \text{CDC}}\\$

Questions?

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