ADULT IMMUNIZATION 2023:
"MILES TO GO BEFORE I SLEEP…"

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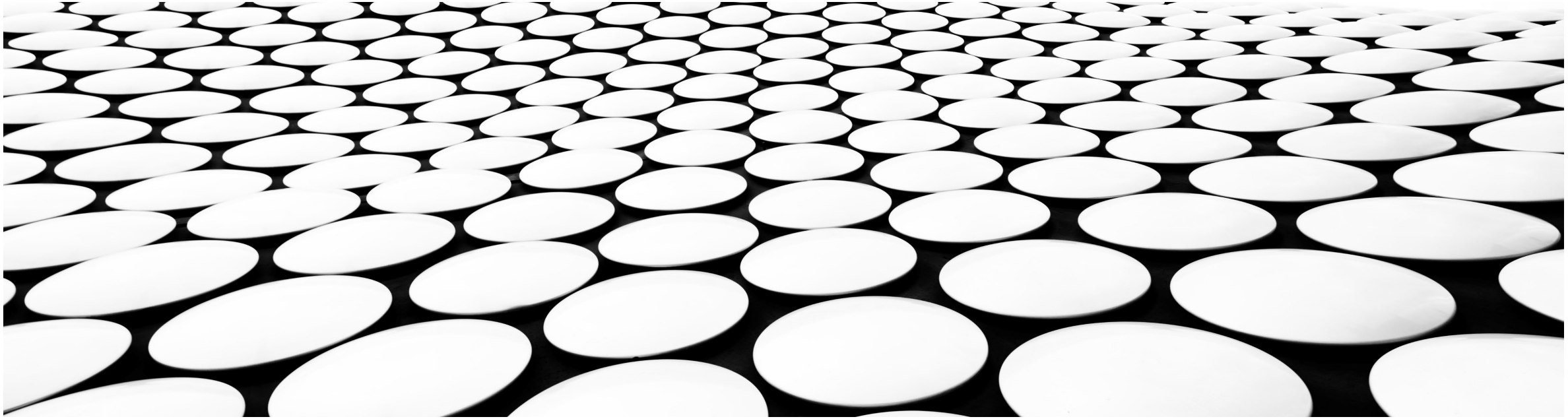


DISCLOSURES

- There is no such thing in medicine or public health as PERFECTION.
- Medical and Public Health recommendations require assessment of benefits and risks in order to make a decision or provide guidance.
- Vaccines entail FAR lower risk than ‘natural infection’ when immunization is done in accord with ACIP recommendations.
- I do not have any financial conflicts of interests relevant to this presentation.
- The recommendations which I make in this presentation are based on my best effort to review, assess and critically synthesize numerous sources of data.
- My recommendations for you are those I would make for my patients, for my family members and for myself.

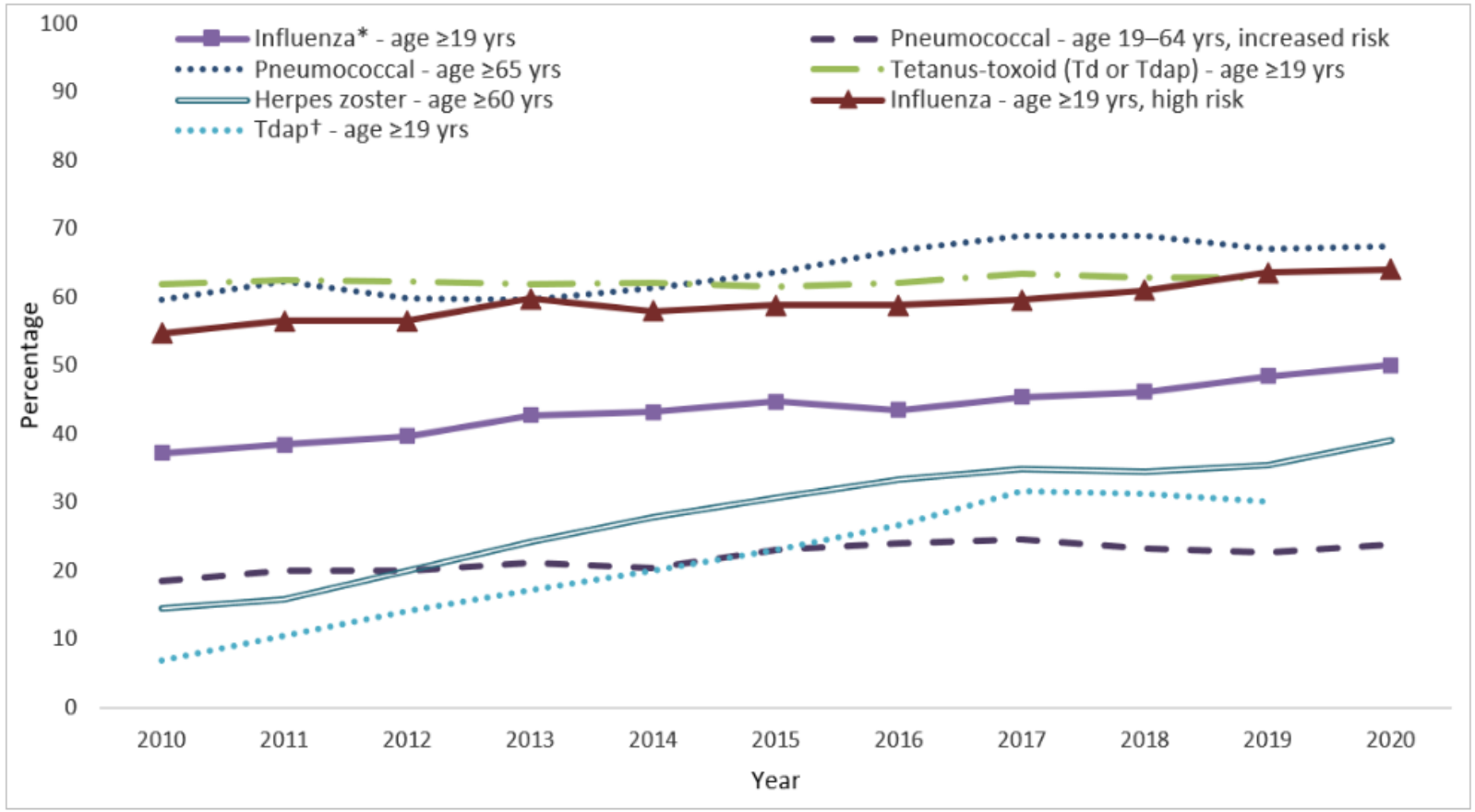
BASIC VACCINOLOGY

- **Vaccine preventable disease**
  - Ongoing endemic disease [Pertussis, Pneumococcal disease, Shingles, Malaria]
  - Outbreaks continue to occur [COVID-19, Influenza, Measles, Mumps, Hep A, Hep B, …]
  - Uncommon disease with significant health impacts [Polio]
- **Vaccines for adults**
  - Concept 1: Risk [OF and FROM] disease may be cumulative at individual level
  - Concept 2: Quantifying vaccine benefits and risks at individual level is challenging
  - Concept 3: Goals= reduce severe disease->reduce disease->reduce transmission
  - Concept 4: High immunization rates MAY translate into population benefits (Community –or Herd- Immunity)
  - Concept 5: Types of Recommendations [ACIP]
    - **RECOMMEND:** All (in a defined population) and without contraindications should receive
    - **SHARED DECISION:** Decision to vaccinate based on risk/benefit discussion (Doc-PT discussion)

OUTLINE

- Adult Schedule Overview
- Changes and Challenges
  - COVID-19
  - Influenza
  - RSV
  - Pneumococcal
  - HBV
- Making recommendations
- IRA Related Changes

FIGURE. Estimated proportion of adults aged ≥19 years who received selected vaccines, by age group and risk status — National Health Interview Survey, United States, 2010–2020



https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/pubs-resources/vaccination-coverage-adults-2019-2020.html

ACIP ADULT SCHEDULE [AGE-BASED- *MODIFIED BY PRESENTER*]

Table 1 COVID-19 vaccination recommendations have changed. Find the latest recommendations at www.cdc.gov/covidschedule

Recommended Adult Immunization Schedule for ages 19 years or older, United States, 2023

Vaccine	19–26 years	27–49 years	50–64 years	≥65 years
COVID-19	*1 dose BiValent Vaccine [expect changes once 2023 fall vaccine authorized by FDA/ACIP recommendations released]*			
Influenza inactivated (IIV4) or Influenza recombinant (RIV4)	1 dose annually			
or				
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

RSV				*(60+ years SDM) 1 dose*

ACIP ADULT SCHEDULE [INDICATION BASED]

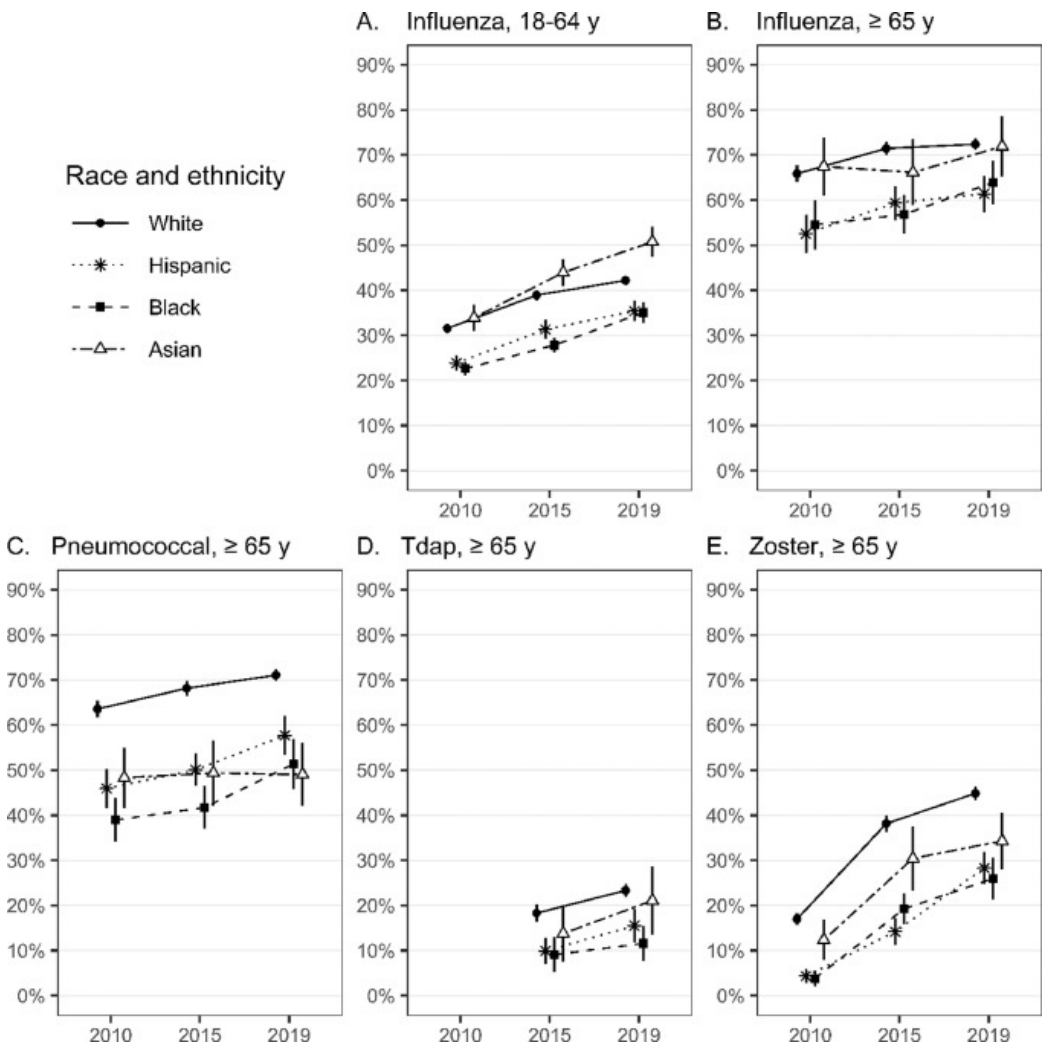
Table 2 Recommended Adult Immunization Schedule by Medical Condition or Other Indication, United States, 2023

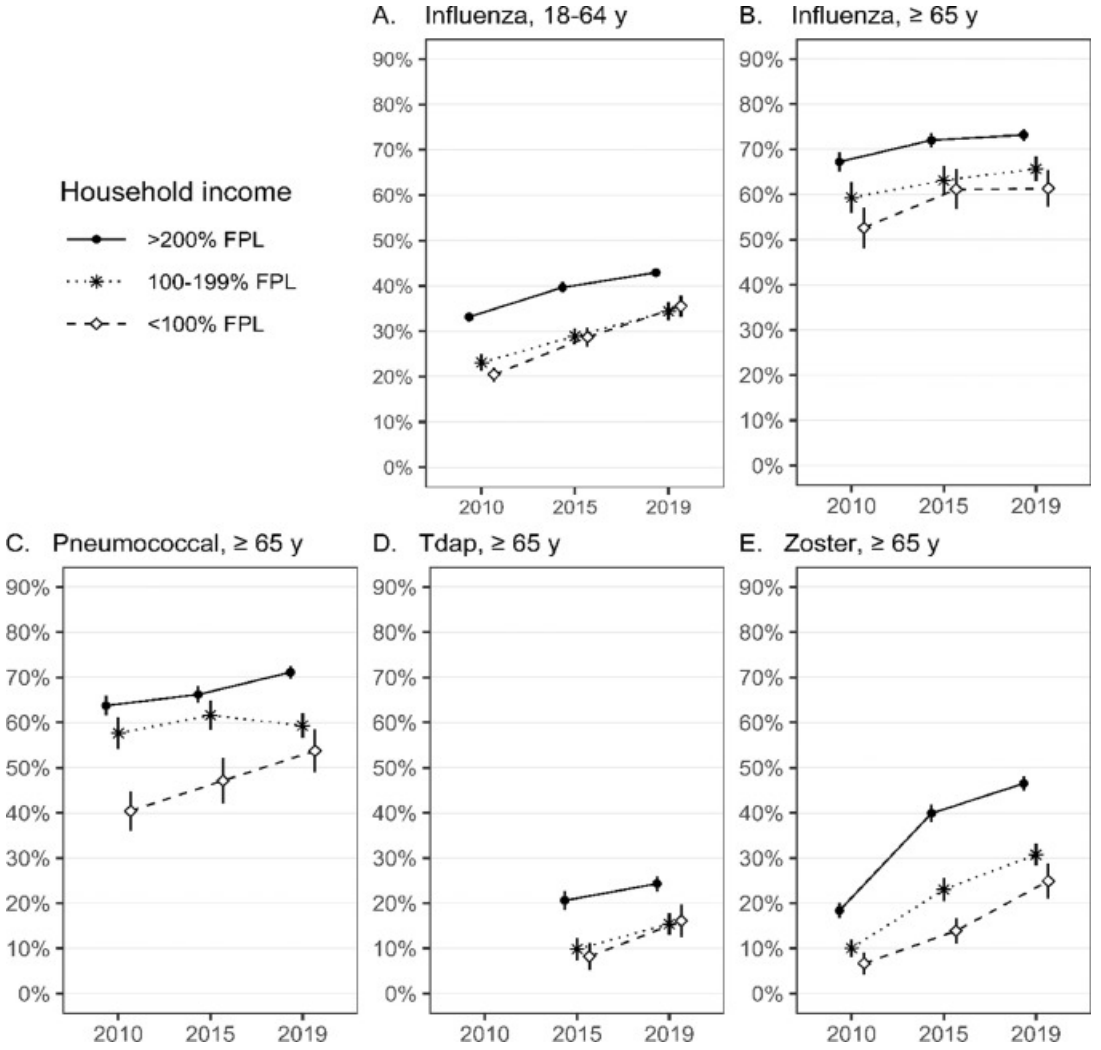
Vaccine	Pregnancy	Immuno-compromised (excluding HIV infection)	HIV infection CD4 percentage and count		Asplenia, complement deficiencies	End-stage renal disease, or on hemodialysis	Heart or lung disease; alcoholism[a]	Chronic liver disease	Diabetes	Health care personnel[b]	Men who have sex with men
			<15% or <200 mm³	≥15% and ≥200 mm³							
COVID-19		See Notes									
IIV4 or RIV4	1 dose annually										
or										or	
LAIV4	Contraindicated					Precaution				1 dose annually	
Tdap or Td	1 dose Tdap each pregnancy	1 dose Tdap, then Td or Tdap booster every 10 years									
MMR	Contraindicated*	Contraindicated		1 or 2 doses depending on indication							
VAR	Contraindicated*	Contraindicated			2 doses						
RZV		2 doses at age ≥19 years			2 doses at age ≥50 years						
HPV	Not Recommended*	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[c] 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 benefit of protection 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.

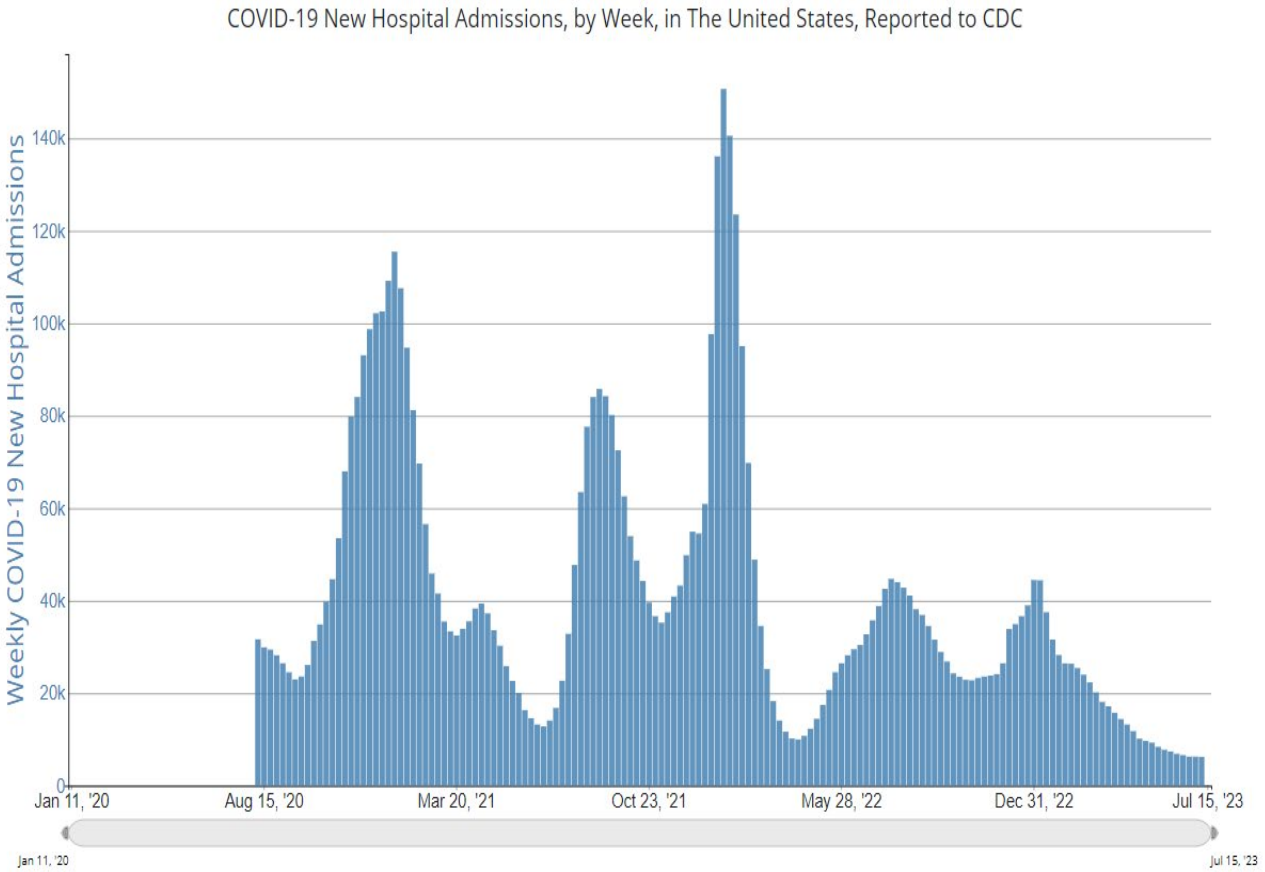
DISPARITIES IN ADULT VACCINATION RATES [RACIAL/ETHNIC, ECONOMIC]

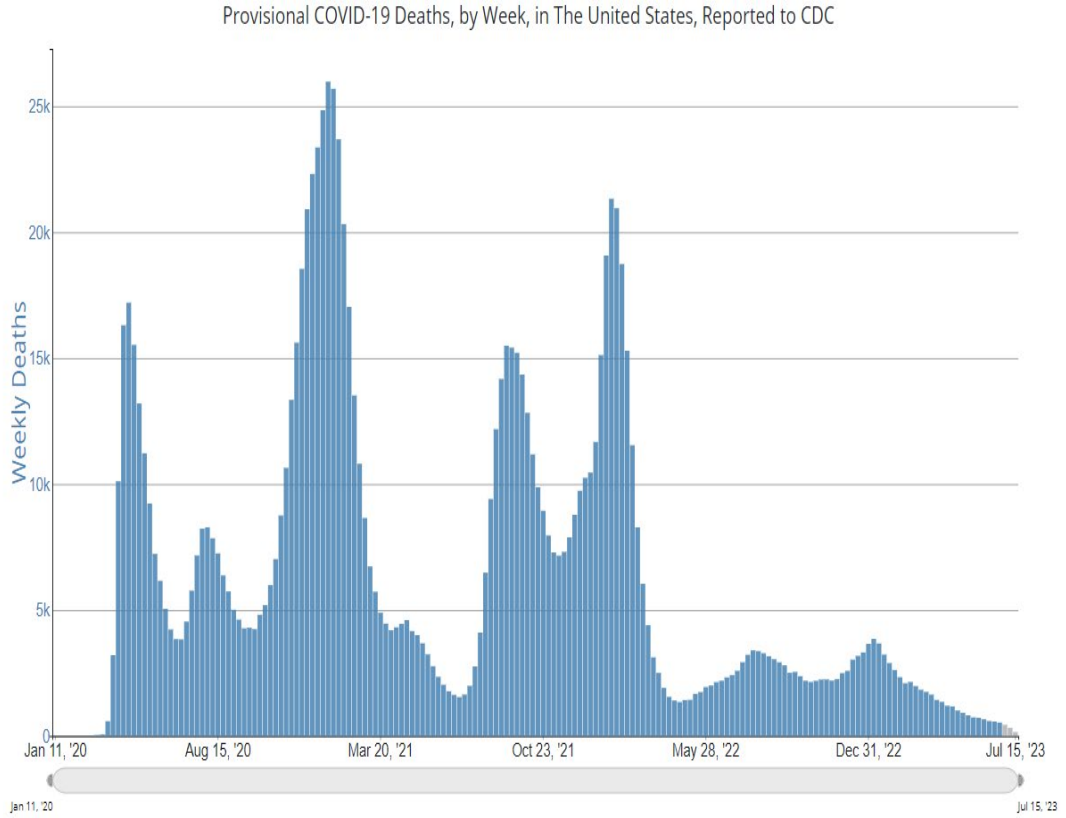




KAWAI, ET.AL. AM J PREV MED. 2021: 61(4) PP. 465-73.

COVID-19 VACCINATION

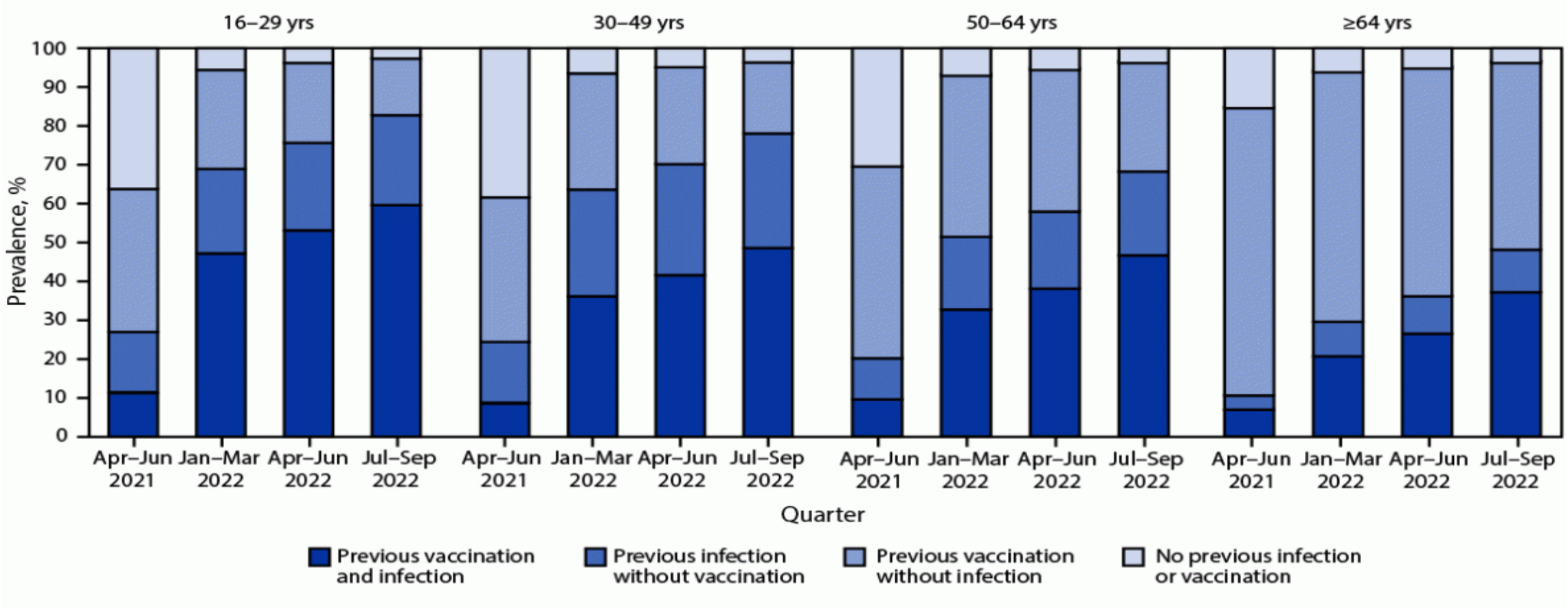




https://covid.cdc.gov/covid-data-tracker/#trends_weeklyhospitaladmissions_select_00

COVID-19 IMMUNITY IN ADULTS

FIGURE 2. Prevalences of vaccine-induced, infection-induced, and hybrid* immunity† against SARS-CoV-2 among blood donors aged ≥16 years, by age group — United States, April 2021–September 2022



https://www.cdc.gov/mmwr/volumes/72/wr/mm7222a3.htm#F1_down

COVID VACCINE EFFECTIVENESS

FIGURE. SARS-CoV-2 infections per 1,000 nursing home residents,* by up-to-date vaccination status† and reporting week — National Healthcare Safety Network, United States, November 20, 2022–January 8, 2023

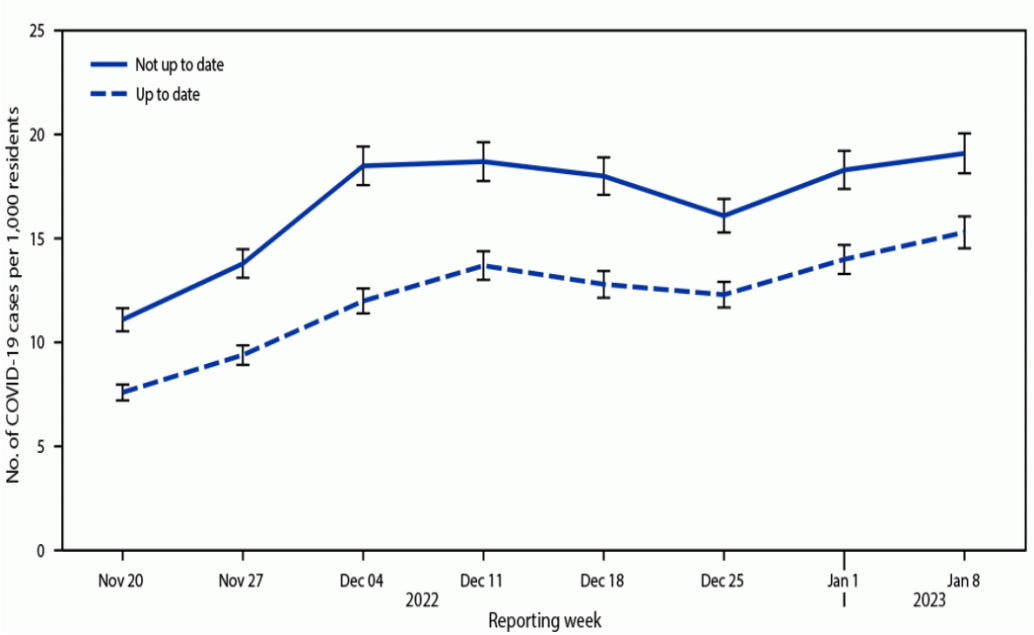


TABLE. Average weekly mortality rates* and rate ratios for unvaccinated adults aged ≥65 years compared with those vaccinated with a bivalent COVID-19 vaccine booster dose,† by time since vaccination and variant period§ — 20 U.S. jurisdictions,¶ September 18, 2022–April 1, 2023

		Vaccination status				
			Vaccinated with bivalent booster dose, by time since vaccination**			
		Unvaccinated	2 wks–2 mos		3–6 mos	
Period (predominant Omicron lineage)	Total	No. of deaths (mortality rate)	No. of deaths (mortality rate)	RR (95% CI)††	No. of deaths (mortality rate)	RR (95% CI)
Sep 18–Nov 5, 2022 (BA.5)	**1,717**	1,623 (13.5)	94 (0.8)	16.3 (13.8–19.1)	NA§§	NA§§
Nov 6, 2022–Jan 21, 2023 (BQ.1/BQ.1.1)	**4,537**	3,532 (18.8)	794 (1.6)	11.4 (9.4–13.9)	211 (1.8)	11.0 (8.4–14.4)
Jan 22–Apr 1, 2023 (XBB.1.5)	**1,907**	1,247 (7.3)	114 (0.9)	8.4 (6.1–11.7)	546 (1.0)	7.3 (6.1–8.7)

¶ The 20 jurisdictions included in this analysis represent 41% of the overall U.S. population: Alabama, Arizona, Colorado, District of Columbia, Georgia, Idaho, Indiana Kentucky, Louisiana, Michigan, Minnesota, Nebraska, New Jersey, New Mexico, New York City, North Carolina, Tennessee, Texas, Utah, and West Virginia.

- Among groups at highest risk for morbidity and mortality from COVID-19, Vaccination reduced risk for morbidity and mortality

https://www.cdc.gov/mmwr/volumes/72/wr/mm7225a4.htm#F1_down
https://www.cdc.gov/mmwr/volumes/72/wr/pdfs/mm7224a6-H.pdf

COVID-19 WHERE ARE WE NOW??

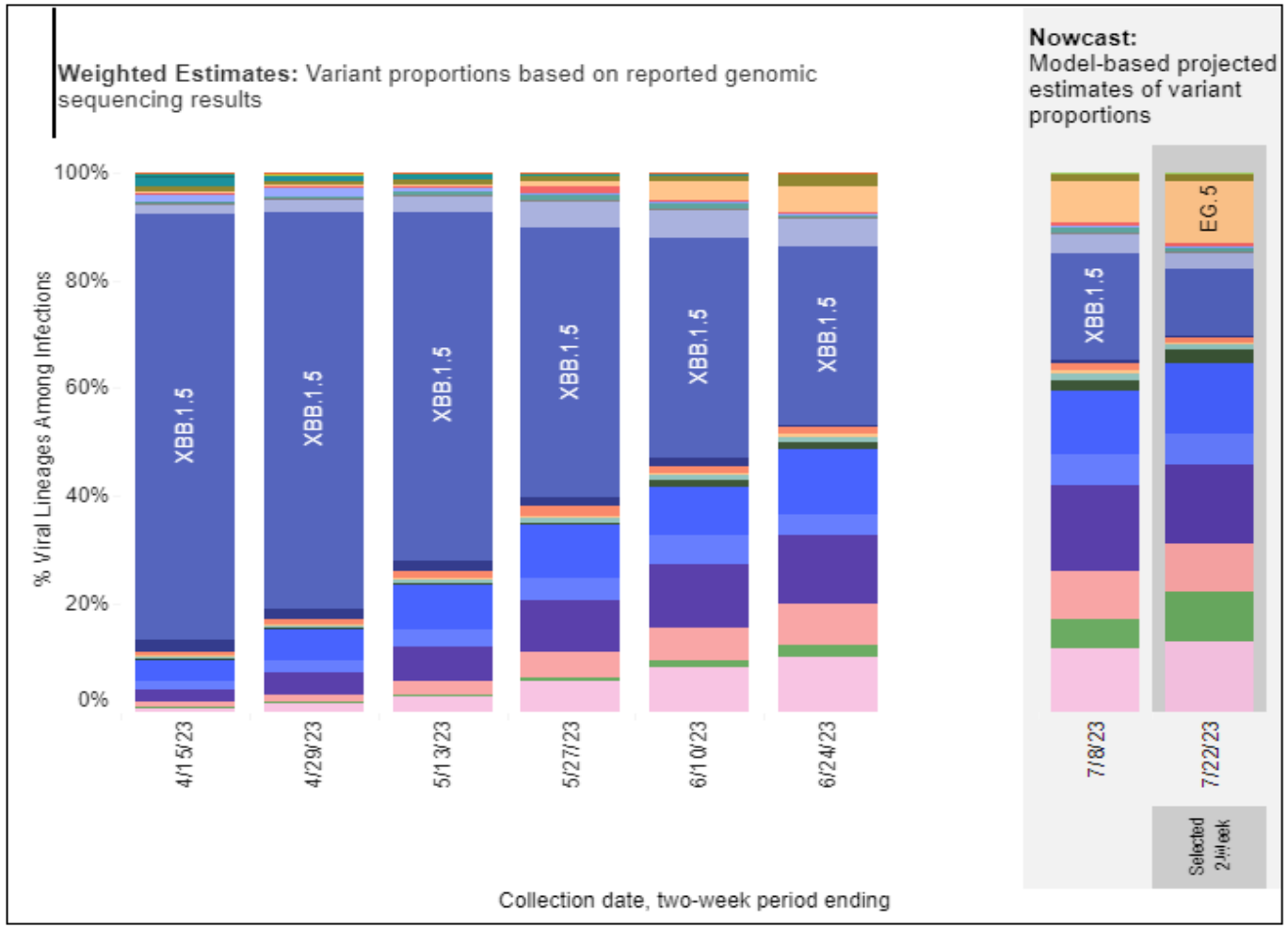
- SARS-CoV2 Continues to circulate worldwide
- Surveillance is not ideal…
  - ADH Data Hub — Updated weekly- passive reporting…
  - COVID-NET [Hospital] — No sites in Arkansas
  - Wastewater — Few sites in Arkansas
- Uptake of recent vaccines [BiValent] has been poor
- Few are implementing **any** form of personal or community protection
  - Masks, Improved Ventilation, …
- Expect new monovalent vaccine this fall [Moderna, Novavax, Pfizer-BioNTec]
  - ACIP vaccine recommendations to follow after FDA approval…

https://experience.arcgis.com/experience/4f55fdd341df4e2f854c14b974d6b350/page/Covid-19/
https://covid.cdc.gov/covid-data-tracker/#hospitalizations-landing

Weighted and Nowcast Estimates in United States for 2-Week Periods in 4/2/2023 – 7/22/2023

Nowcast Estimates in United States for 7/9/2023 – 7/22/2023

Hover over (or tap in mobile) any lineage of interest to see the amount of uncertainty in that lineage's estimate.



USA

WHO label	Lineage #	%Total	95%PI
Omicron	XBB.1.16	14.8%	12.2-17.8%
	XBB.1.9.1	13.2%	8.3-20.3%
	XBB.2.3	13.0%	10.4-16.1%
	XBB.1.5	12.3%	10.2-14.7%
	EG.5	11.4%	8.3-15.3%
	XBB.1.16.6	9.3%	5.4-15.4%
	XBB.1.16.1	8.8%	7.4-10.4%
	XBB.1.9.2	5.6%	4.0-7.8%
	XBB	3.0%	1.8-4.9%
	XBB.1.5.72	2.2%	1.2-3.9%
	CH.1.1	1.7%	0.8-3.6%
	FE.1.1	1.1%	0.6-2.0%
	XBB.1.5.68	1.0%	0.6-1.7%
	XBB.1.5.10	1.0%	0.6-1.6%
	EU.1.1	0.6%	0.3-1.0%
	XBB.1.5.59	0.4%	0.2-1.0%
	XBB.1.5.1	0.3%	0.2-0.5%
	FD.2	0.0%	0.0-0.1%
	BA.2	0.0%	0.0-0.0%
	BN.1	0.0%	0.0-0.0%
	BQ.1.1	0.0%	0.0-0.0%
	BA.5	0.0%	0.0-0.0%
	BQ.1	0.0%	0.0-0.0%
	BA.2.75	0.0%	0.0-0.0%
Other	Other*	0.1%	0.0-0.1%

* Enumerated lineages are US VOC and lineages circulating above 1% nationally in at least one 2-week period. "Other" represents the aggregation of lineages which are circulating <1% nationally during all 2-week periods displayed.

\# BA.1, BA.3 and their sublineages (except BA.1.1 and its sublineages) are aggregated with B.1.1.529. Except BA.2.12.1, BA.2.75, XBB and their sublineages, BA.2 sublineages are aggregated with BA.2. Except BA.2.75.2, CH.1.1 and BN.1, BA.2.75 sublineages are aggregated with BA.2.75. Except BA.4.6, sublineages of BA.4 are aggregated to BA.4. Except BF.7, BF.11, BA.5.2.6, BQ.1 and BQ.1.1, sublineages of BA.5 are aggregated to BA.5. Except the lineages shown and their sublineages, sublineages c XBB are aggregated to XBB. Except XBB.1.5.1, XBB.1.5.10, FD.2, EU.1.1, XBB.1.5.68 and XBB.1.5.72, sublineages of XBB.1.5 are aggregated to XBB.1.5. Except XBB.1.16.1, sublineages of XBB.1.16 are aggregated to XBB.1.16. Except FE.1.1, sublineages c XBB.1.18.1 are aggregated to XBB. For all the other lineages listed, their sublineages are aggregated to the listed parental lineages respectively. Previously, EU.1.1, XBB.1.5.68 and XBB.1.5.72 was aggregated to XBB.1.5, FE.1.1 was aggregated to XBB an EG.5 was aggregated to XBB.1.9.2. Lineages BA.2.75.2, XBB, XBB.1.5 , XBB.1.5.1, XBB.1.5.10, FD.2, XBB.1.9.1, XBB.1.9.2, XBB.1.16, XBB.1.16.1, XBB.2.3, BN.1, BA.4.6, BF.7, BF.11, BA.5.2.6 ,BQ.1.1, EU.1.1, XBB.1.5.68, FE.1.1, EG.5 and XBB.1.5.72 contain the spike substitution R346T.

https://covid.cdc.gov/covid-data-tracker/#variant-proportions

RISK OF INFECTION VS. RISK OF VACCINATION

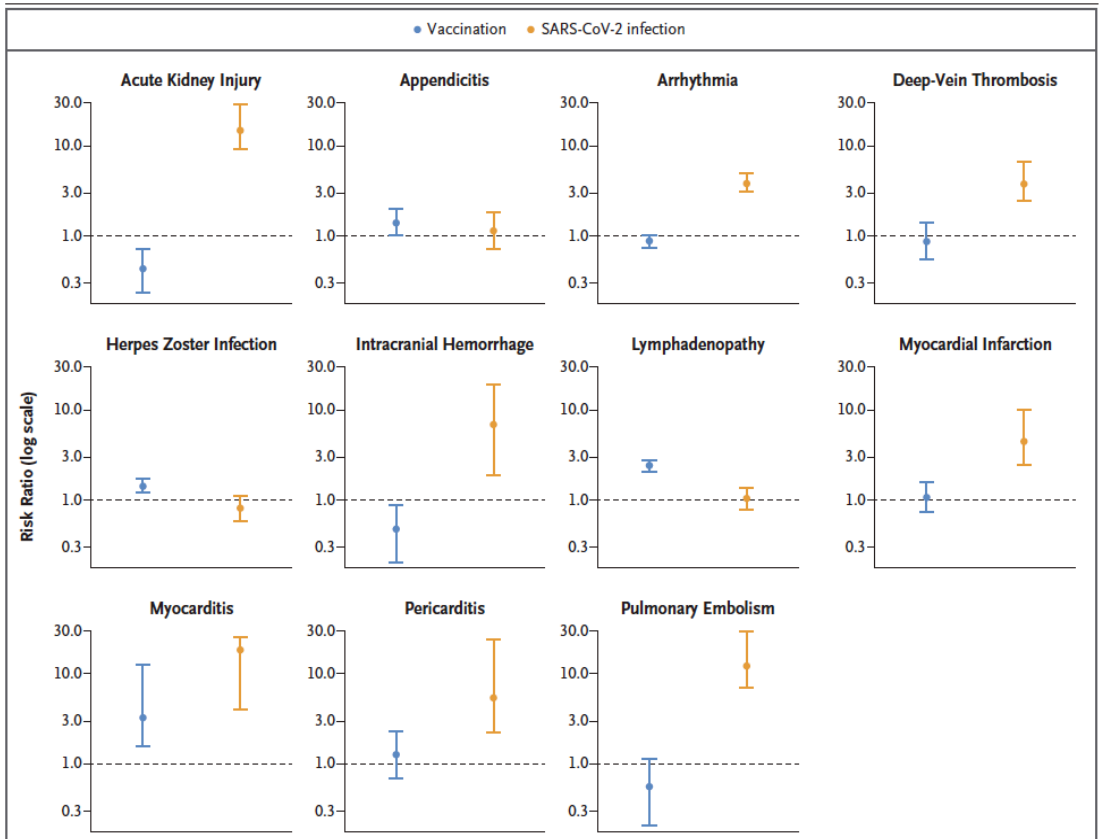


Figure 3. Risk Ratios for Adverse Events after Vaccination or SARS-CoV-2 Infection.

Estimated risk ratios for adverse events after vaccination or SARS-CoV-2 infection are shown. The risk ratio on the y axis is presented on a logarithmic scale to facilitate comparison of both increased and decreased risk. I bars indicate 95% confidence intervals.

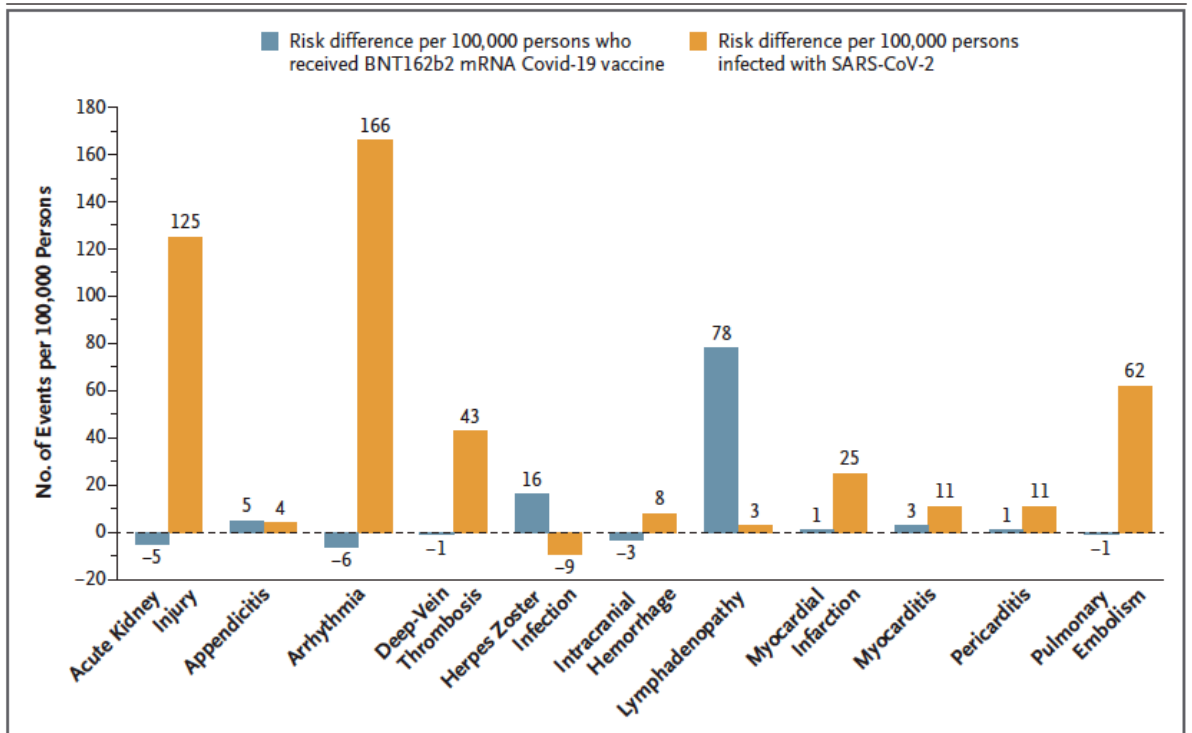


Figure 4. Absolute Excess Risk of Various Adverse Events after Vaccination or SARS-CoV-2 Infection.

Point estimates of the risk differences for selected adverse events are shown. Estimates were derived 42 days after vaccination or SARS-CoV-2 infection with the use of the Kaplan–Meier estimator. Risk differences are shown per 100,000 persons and rounded to the nearest integer. Negative differences (decreased risk) are represented as negative values on the y axis, and positive differences (increased risk) are represented as positive values on the y axis. The abbreviation mRNA denotes messenger RNA.

Barda et al., NEJM 2021

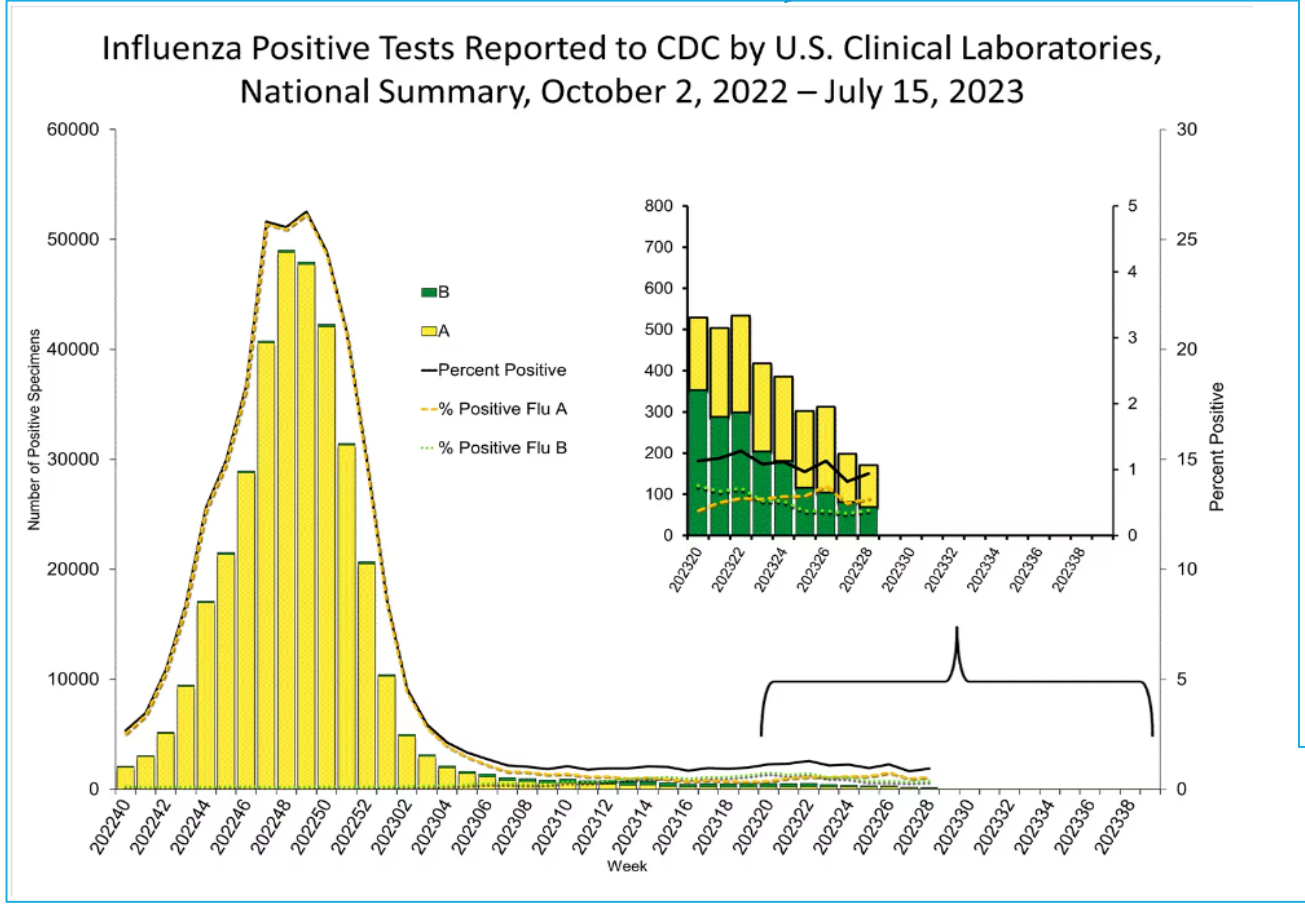
Note: ‘Long COVID’ outcomes not assessed…

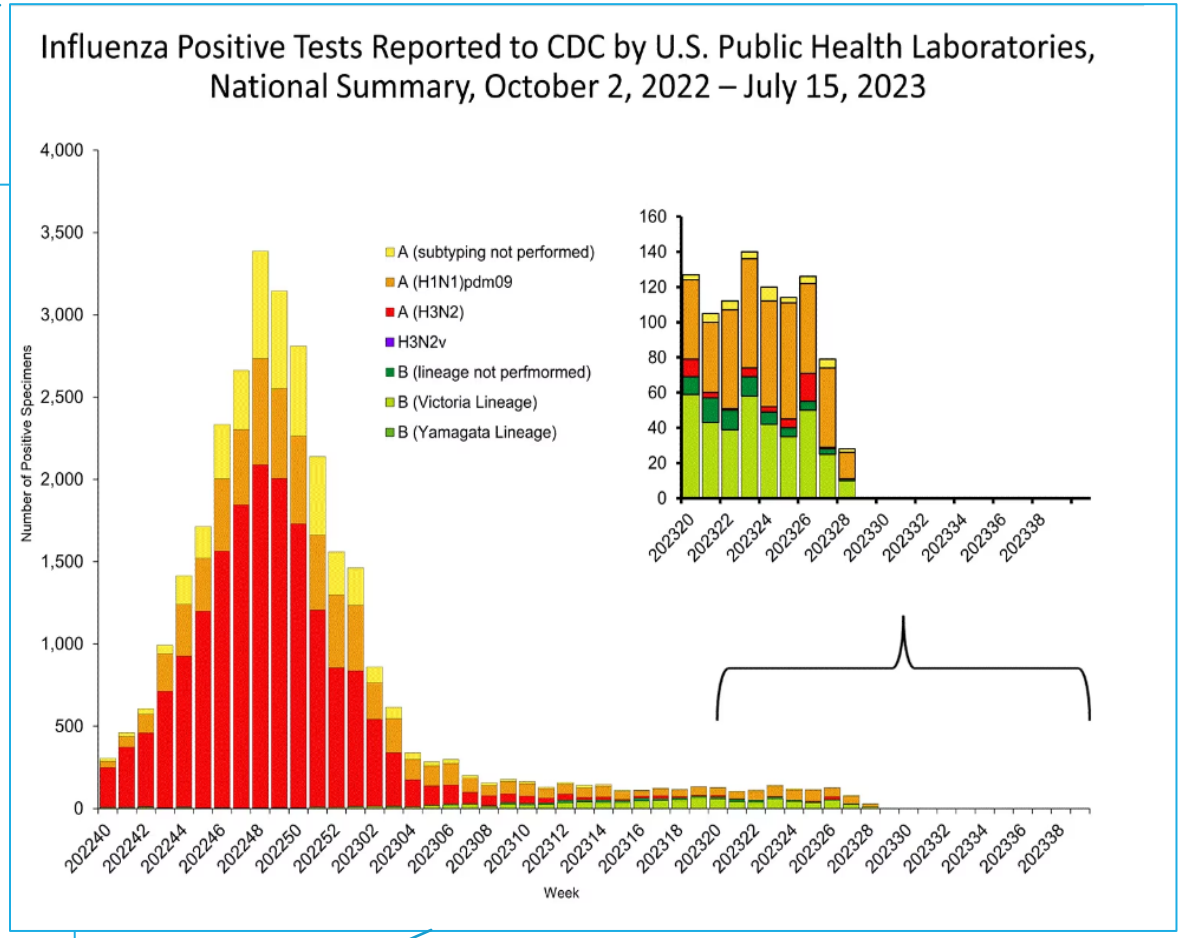
COVID-19 VACCINATION

- Current vaccines based on XBB.1.5 Omicron are being developed
  - Expect FDA action later this summer/early fall followed by ACIP recommendations
- What DO we know:
  - Persons 65+ and immune compromised patients have highest rate of M&M

    [Not in scope but concerns re: very young as well as no 'natural immunity'…]
  - Vaccinated persons have less hospitalizations and deaths due to COVID-19 than unvaccinated
  - Vaccine-induced protection with current vaccines is not durable (beyond months)
  - Vaccine adverse effects are uncommon
- Hopes for the future
  - More effective vaccines [against infection, more durable immunity, 'pan-corona' vaccines…]
  - More antivirals, monoclonal Ab and/or other effective therapeutics…
  - Commitment to better 'indoor' air quality
  - The Beatles will return to prominence [ergo: All we need is love…]

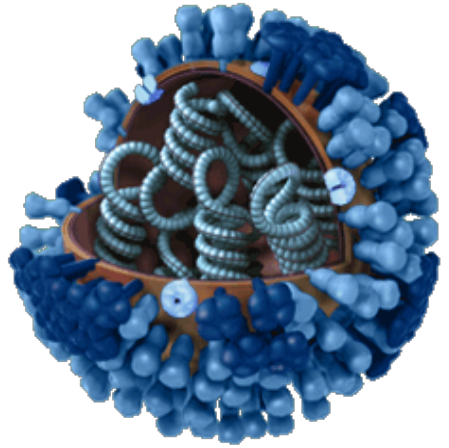
INFLUENZA





https://www.cdc.gov/flu/weekly/index.htm

INFLUENZA



- Influenza: Orthomyxoviridae family [enveloped RNA virus]
  - 3 types based on surface Ag [HA, NA] + internal structure
    - A: Multiple hosts – Birds, Mammals [Man]. Many HA, NA types
    - B: Humans (only)
    - C: Not a significant cause of human disease
  - Vaccinate from 'Vaccine available' thru 'no disease in community'
- Up to 50,000 deaths annually in US from Influenza
  - 200K+ assoc. hospitalizations, chronic illnesses exacerbations
  - > 90% seasonal influenza M&M occurs in adults > 65 years
  - H3N2 strains cause greatest morbidity/mortality in adults
- Vaccination= MOST effective intervention vs. illness, death

http://www.cdc.gov/flu/avian/gen-info/flu-viruses.htm

INFLUENZA DISEASE AND VACCINE BENEFITS

Table 1: Vaccine effectiveness against laboratory confirmed influenza A in inpatient and emergency department (ED) settings, September 13, 2022-January 25, 2023

Vaccine Effectiveness						
	Influenza positive		Influenza negative[1]		Adjusted[2]	
	N vaccinated /Total	(%)	N vaccinated /Total	(%)	VE %	95% CI
Influenza A All 6 mos – 17 years	123/640	19	750/2256	33	**49**	(36 to 60)
Inpatient	19/131	15	288/913	32	**68**	(46 to 81)
ED	104/507	21	461/1330	35	**42**	(25 to 56)
A/H3N2	98/478	21	750/2256	33	**45**	(29 to 58)
A/H1N1pdm09	23/139	17	750/2256	33	**56**	(28 to 72)

Vaccine effectiveness is multifactorial

- Match between ‘disease’ and ‘vaccine’ strains
- ~2 weeks following vaccine to develop immunity
- “Substrate matters…”
- 2022-23:
  - US (Wisconsin) 2 studies 54% reduction med attended Flu A in <65 y, and 71% Sx flu A in <18 y.
  - Interim results 6 EU studies: ≥27% reduction Flu A, ≥50% in Flu B [*greater in kids*]

HTTPS://WWW.CDC.GOV/FLU/PREVENT/INDEX.HTML
HTTPS://WWW.CDC.GOV/MMWR/VOLUMES/72/WR/MM7208A1.HTM
HTTPS://WWW.NCBI.NLM.NIH.GOV/PMC/ARTICLES/PMC10283457/#:~:TEXT=INTERIM%20RESULTS%20FROM%20SIX%20EUROPEAN,WITH%20HIGHER%20REDUCTIONS%20AMONG%20CHILDREN.

US INFLUENZA VACCINES

- Multiple flu vaccines approved. *"Don't let perfection be the enemy of the good!!"*
  - All vaccines quadrivalent since 2021-22
  - Egg allergy: No longer a consideration

  IMMUNIZE ALL ADULTS with vaccine approved for (this specific) patient!
- **Personalized vaccinology opportunities:**
  - HD, Adjuvanted vaccines provide equal or better protection in persons 65+ years
  - Recombinant HA vaccine contains no egg protein
  - Some studies suggest Cell Culture, Recombinant vaccines have greater efficacy than egg-based
  - LAIV available for ages 2-49 years who are 'needle resistant'
- All >6 months old need vaccination but we need to acknowledge and address risk groups

https://www.cdc.gov/flu/professionals/vaccination/index.htm
http://www.nejm.org/doi/full/10.1056/NEJMoa1315727
https://academic.oup.com/cid/article/73/11/e4251/5992287
https://academic.oup.com/jid/article/220/8/1237/5250956

INFLUENZA RISK GROUPS:

- HEALTHCARE WORKERS
  - High risk for disease (symptomatic and asymptomatic)
  - High risk for transmission
  - If sick, not available to provide healthcare…
- PATIENTS AT HIGHEST RISK (Spread +/- SEVERE ILLNESS)
  - **Pregnant women and women to 2 weeks postpartum**
  - Newborns and children < 2 years
  - Race/Ethnicity
  - Age 65+ years
  - "Medical Comorbidities" (including BMI 40+ kg/m^2)
  - Immune compromised
  - Household contacts of high-risk
  - Long-term care, institutionalized, crowded living conditions

https://www.cdc.gov/flu/prevent/index.html

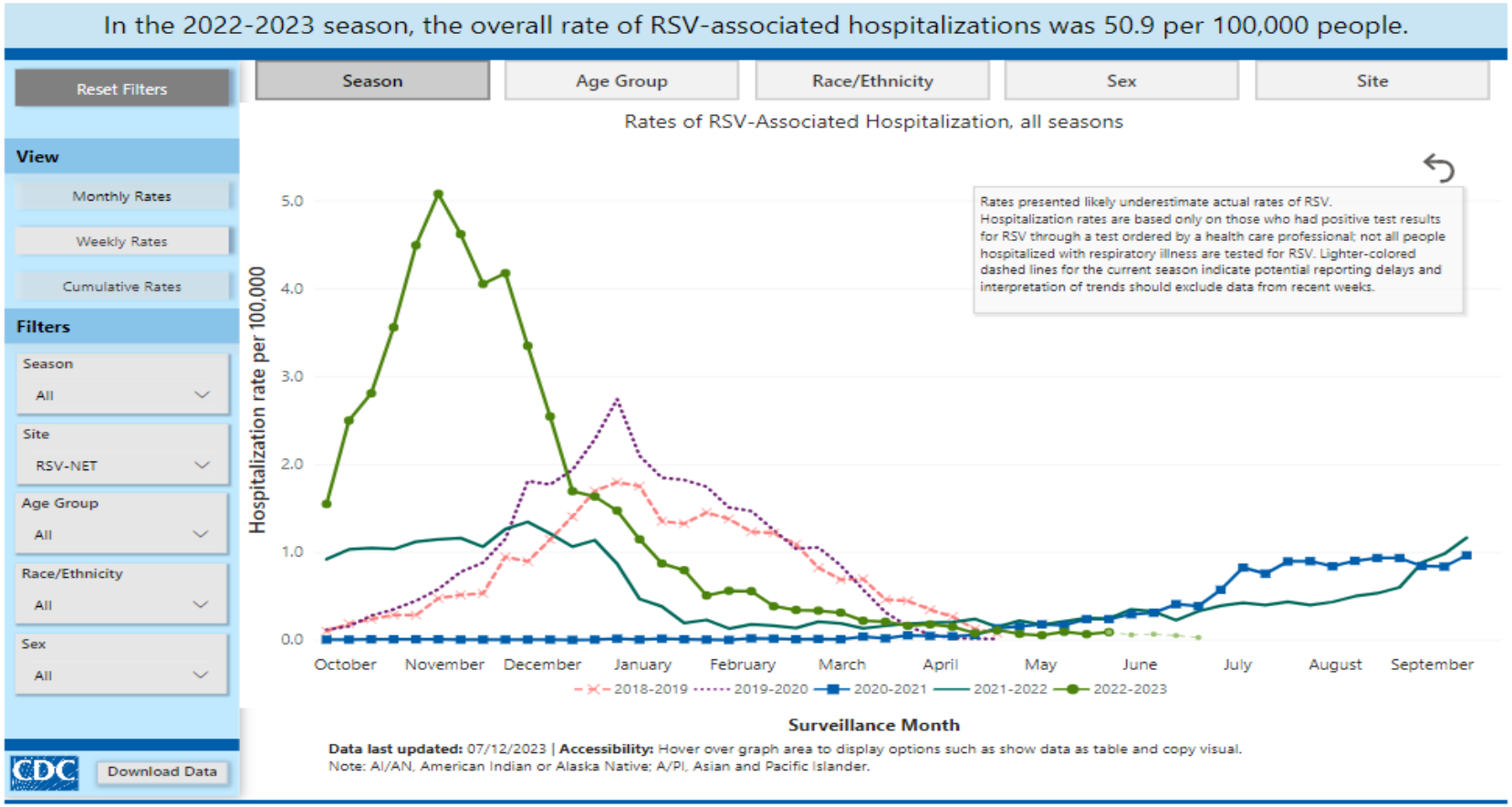
INFLUENZA

Crystal ball re: ongoing research. Be looking for…

- New vaccine platforms
- ‘Universal’ influenza vaccines
- Pandemic influenza vaccines
- Needle-free vaccination technologies
- Combination vaccines [COVID-19, Influenza]

https://www.cdc.gov/flu/vaccines-work/effectiveness-studies.htm
https://www.cdc.gov/flu/prevent/advances.htm
https://www.niaid.nih.gov/diseases-conditions/influenza-vaccines

RSV AND RSV VACCINATION



https://www.cdc.gov/rsv/research/rsv-net/dashboard.html

RSV= RESPIRATORY SYNCYTIAL VIRUS

- Common respiratory virus Symptoms overlap with other respiratory pathogens
  - Enveloped negative strand RNA virus. Paramyxoviridae family. 2 major subtypes (A,B) with numerous genotypes
- Illness
  - Infants: most common cause Bronchiolitis and Pneumonia in children <1 in US.

    Highest risk: premature, <6mo, heart or lung disease
  - Most who are infected have mild upper respiratory illness [a 'Cold']
  - Adults: older adults + persons with chronic heart disease, chronic lung disease, immune suppression ^^ risk severe dz
  - Immunity after infection is NOT durable…
- Epidemiology
  - Children: ~2.1 million outpatient visits and 58-80,000 hospitalizations annually in children <5 years
  - Adults: 60-160,000 hospitalizations annually → 6-10,000 deaths
  - Likely underestimates (based on test +).
  - Antigen tests highly sensitive in kids but NOT in adults. PCR more sensitive in both adults & children.

https://www.cdc.gov/rsv/index.html#:~:text=Respiratory%20Syncytial%20Virus%20(RSV)%20Infection,for%20infants%20and%20older%20adults.

RSV PREVENTION: TOOLS IN EVOLUTION

- Palivizumab — Long-acting monoclonal antibody available since 1998 for prevention of serious LRTI due to RSV in highest risk infants.
- Vaccines — FDA Approved 5/3 [GSK] then 5/31 [Pfizer]; ACIP Review/Recommendation 6/29/2023:
  1 dose RSV Vaccine for adults 60+ using Shared Clinical Decision Making

  FDA VRBPAC recommended Pfizer vaccine for pregnant women 5/19 [*FDA review in progress*]
  ACIP initial review 8/3
- Nirsevimab — Long-acting monoclonal antibody approved by FDA 6/12/2023 for prevention of RSV
  ACIP review 8/3 and recommendations to come…

https://publications.aap.org/pediatrics/article/134/2/415/33013/Updated-Guidance-for-Palivizumab-Prophylaxis-Among?autologincheck=redirected
https://www.nejm.org/doi/full/10.1056/NEJMoa2110275

RSV PREFUSION F VACCINE [PFIZER= RENOIR TRIAL]

- Vaccine: 120 ug= 60ug RSV A (Ontario Genotype) and 60 ug RSV B (Buenos Aires genotype) antigens, IM
- Enrollment 8/31/2021- 7/14/2022, Data cutoff 7/14/2022. Median age 67 years
- Phase 3 multicenter worldwide PC RCT 1:1, adults 60+ Interim analysis 34284 participants (17215 V, 17089 P)
- Primary endpoints: Efficacy against RSV LRTI with 2+ symptoms, + PCR: 11 vs 33 VE 66.7% (28.8-85.8%)

  Efficacy against RSV-associated acute RTI, + PCR: 22 vs 58 VE 62.1% (37.1-77.9%)
- Local reactions to vaccine 12% v PBO 7%; systemic reactions similar (27% v 26%)
- SAE-V: Delayed allergic reaction 7 d. post-vax ['recovery same day']

  Diplopia, ophthalmoplegia, paresthesias in DM pt. 8 d. post-vax, clin. Dx GBS (Miller-Fischer type) ['recovered']

  MI 6 d. post vaccination- angioplasty, later Dx AIDP began 7 d. post-vax ['recovering']
- High efficacy, low AE. Limitations: IC patients were excluded. Insufficient power to determine effect on severe RSV. Current study data limited to single RSV season. Few in study >70, even fewer > 80.

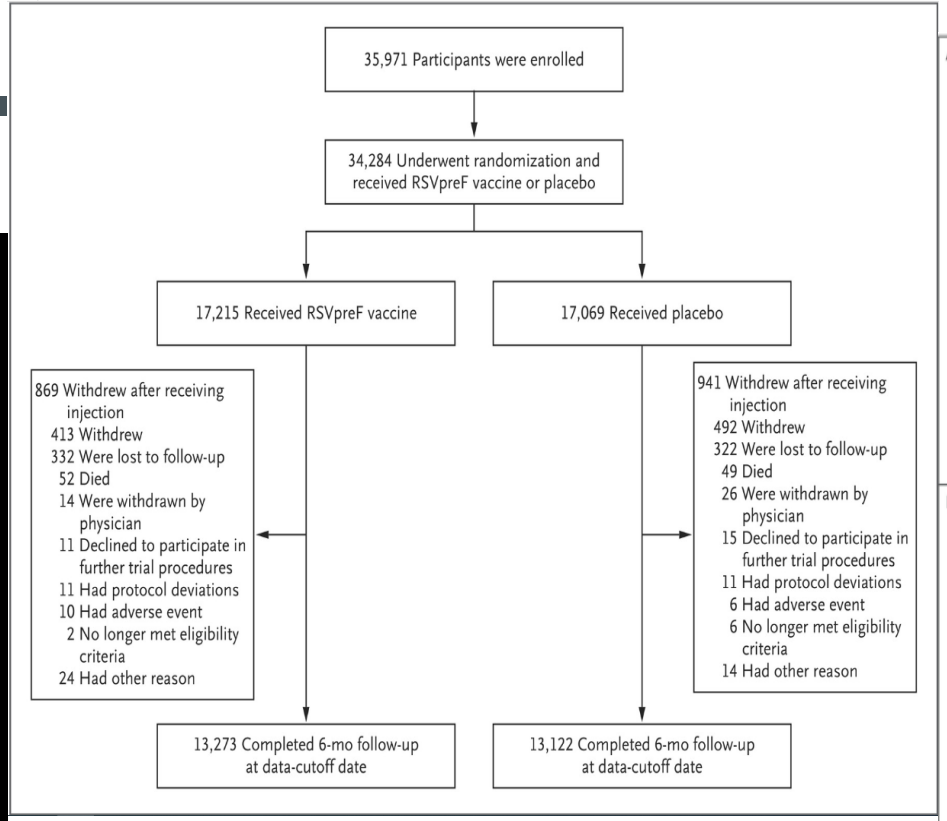
https://www.nejm.org/doi/full/10.1056/NEJMoa2213836

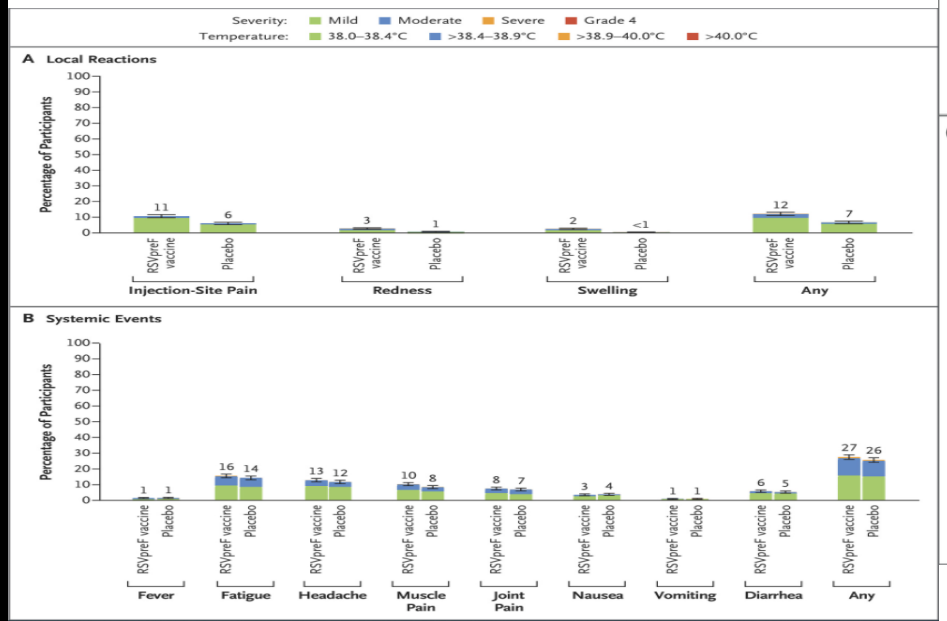
PFIZER= RENOIR

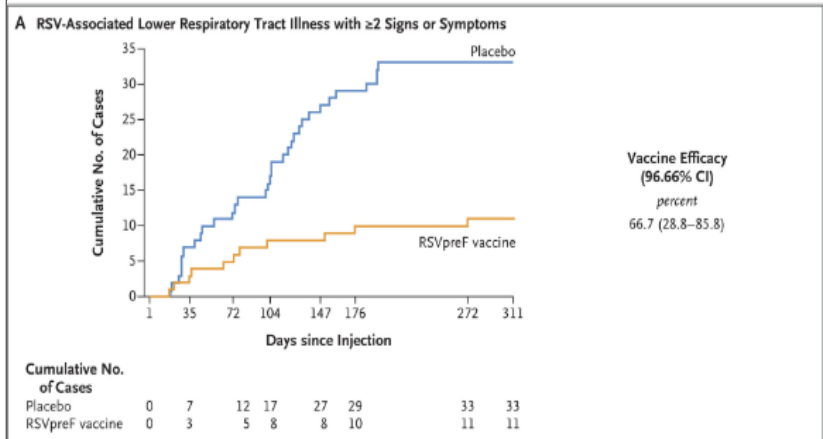
Table 1. Demographic and Clinical Characteristics of the Participants at Baseline (Safety Population).*

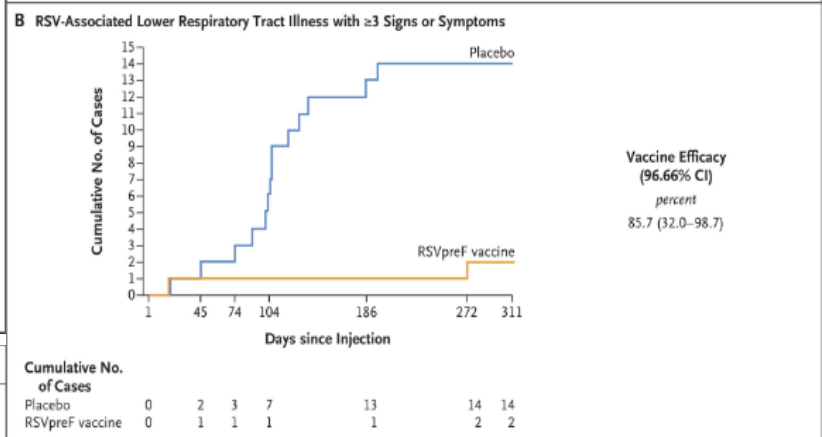
Characteristic	RSVpreF Vaccine (N=17,215)	Placebo (N=17,069)	Total (N=34,284)
Age			
Mean — yr	68.3±6.14	68.3±6.18	68.3±6.16
Median (range) — yr	67 (59–95)	67 (60–97)	67 (59–97)
Age group — no. (%)			
60–69 yr†	10,757 (62.5)	10,680 (62.6)	21,437 (62.5)
70–79 yr	5,488 (31.9)	5,431 (31.8)	10,919 (31.8)
≥80 yr	970 (5.6)	958 (5.6)	1,928 (5.6)
Male sex — no. (%)	8,800 (51.1)	8,601 (50.4)	17,401 (50.8)
Race or ethnic group — no. (%)‡			
White	13,475 (78.3)	13,360 (78.3)	26,835 (78.3)
Black	2,206 (12.8)	2,207 (12.9)	4,413 (12.9)
Asian	1,352 (7.9)	1,333 (7.8)	2,685 (7.8)
Multiracial	44 (0.3)	36 (0.2)	80 (0.2)
Race not reported	56 (0.3)	50 (0.3)	106 (0.3)
Unknown	28 (0.2)	32 (0.2)	60 (0.2)
Not Hispanic or Latinx	10,740 (62.4)	10,715 (62.8)	21,455 (62.6)
Hispanic or Latinx	6,384 (37.1)	6,260 (36.7)	12,644 (36.9)
American Indian or Alaska Native	44 (0.3)	36 (0.2)	80 (0.2)
Native Hawaiian or other Pacific Islander	10 (<0.1)	15 (<0.1)	25 (0.1)
Ethnic group not reported	91 (0.5)	94 (0.6)	185 (0.5)
Country — no. (%)			
United States	10,319 (59.9)	10,182 (59.7)	20,501 (59.8)
Argentina	3,660 (21.3)	3,657 (21.4)	7,317 (21.3)
Japan	1,159 (6.7)	1,156 (6.8)	2,315 (6.8)
The Netherlands	687 (4.0)	681 (4.0)	1,368 (4.0)
Canada	509 (3.0)	506 (3.0)	1,015 (3.0)
South Africa	495 (2.9)	497 (2.9)	992 (2.9)
Finland	386 (2.2)	390 (2.3)	776 (2.3)
Prespecified high-risk condition — no. (%)			
≥1 Prespecified high-risk condition	8,867 (51.5)	8,831 (51.7)	17,698 (51.6)
Current tobacco use	2,642 (15.3)	2,571 (15.1)	5,213 (15.2)
Diabetes	3,224 (18.7)	3,284 (19.2)	6,508 (19.0)
Lung disease§	1,956 (11.4)	2,040 (12.0)	3,996 (11.7)
Heart disease¶	2,221 (12.9)	2,233 (13.1)	4,454 (13.0)
Liver disease	335 (1.9)	329 (1.9)	664 (1.9)
Renal disease	502 (2.9)	459 (2.7)	961 (2.8)
≥1 Chronic cardiopulmonary condition	2,595 (15.1)	2,640 (15.5)	5,235 (15.3)
Asthma	1,541 (9.0)	1,508 (8.8)	3,049 (8.9)
COPD	1,012 (5.9)	1,080 (6.3)	2,092 (6.1)
Congestive heart failure	293 (1.7)	307 (1.8)	600 (1.8)
No prespecified high-risk condition — no. (%)	8,348 (48.5)	8,238 (48.3)	16,586 (48.4)

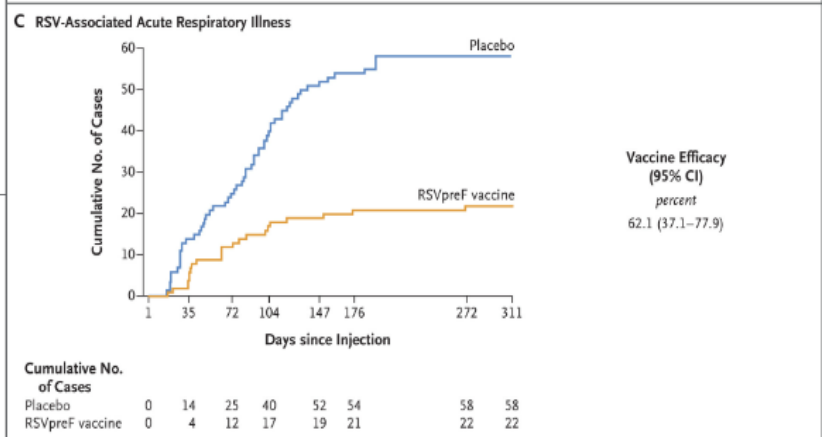
* Plus–minus values are means ±SD. The safety population consisted of all enrolled participants who received respiratory syncytial virus prefusion F protein (RSVpreF) vaccine or placebo. Percentages may not total 100 because of rounding. COPD denotes chronic obstructive pulmonary disease.
† This age group includes one 59-year-old participant.
‡ Race or ethnic group was reported by the participants.
§ This category includes COPD and other lung diseases.
¶ This category includes congestive heart failure and other heart diseases.











RSV PREFUSION F VACCINE [GSK= ARESVI-006 TRIAL]

- Vaccine: 0.5 mL dose $AS01_E$-Adjuvanted RSV prefusion F based candidate vaccine (RSVPreF3OA) [120 ug antigen]
- Enrollment Data cutoff Median age
- Phase 3 multicenter international PC RCT 1:1, adults 60+ Interim analysis 24966 participants (12,467 V, 12,499 P)
- Primary endpoint: Efficacy against RSV LRTI [2+ sx], + PCR: 7 vs 40 VE 82.6% (57.9-94.1%)
- Secondary endpoints: Efficacy v. RSV-associated acute RTI (71.7, ci 56.2-82.3%), severe RSV LRTI (94.1%, ci 62-4-99.9%), RSV LRTI by subtype (2/3 infections RSV B subtype)
- Local reactions: More solicited, unsolicited reactions in vaccine recipients, #1 pain (60.9 v 9.3%)
- SAE-V: Some imbalance between V, PBO recipients: M-S d/o 10 v 5, nervous d/o 5 v 3, parenchymal lung 3 v 1
- High efficacy, low SAE. Limitations: IC patients were excluded. Current study data limited to single RSV season. Too few in study >80, frail.

https://www.nejm.org/doi/full/10.1056/NEJMoa2209604

GSK= ARESVI-006

Table 1. Characteristics of the Participants at Baseline (Exposed Population).*

Characteristic	RSVPreF3 OA Group (N=12,467)	Placebo Group (N=12,499)
Age		
Mean — yr	69.5±6.5	69.6±6.4
Distribution — no. (%)		
≥70 yr	5,504 (44.1)	5,519 (44.2)
≥80 yr	1,017 (8.2)	1,028 (8.2)
60–69 yr	6,963 (55.9)	6,980 (55.8)
70–79 yr	4,487 (36.0)	4,491 (35.9)
Female sex — no. (%)	6,488 (52.0)	6,427 (51.4)
Race — no. (%)†		
Black	1,064 (8.5)	1,101 (8.8)
Asian	953 (7.6)	956 (7.6)
White	9,887 (79.3)	9,932 (79.5)
Other	563 (4.5)	510 (4.1)
Geographic region — no. (%)‡		
Northern Hemisphere	11,496 (92.2)	11,522 (92.2)
Southern Hemisphere	971 (7.8)	977 (7.8)
Type of residence — no. (%)		
Community	12,306 (98.7)	12,351 (98.8)
Long-term care facility	161 (1.3)	148 (1.2)
Frailty status — no. (%)§		
Frail	189 (1.5)	177 (1.4)
Prefrail	4,793 (38.4)	4,781 (38.3)
Fit	7,464 (59.9)	7,521 (60.2)
Unknown	21 (0.2)	20 (0.2)
Charlson comorbidity index¶		
Mean	3.2±1.2	3.2±1.2
Distribution — no. (%)		
Low or medium risk	8,235 (66.1)	8,368 (66.9)
High risk	4,232 (33.9)	4,131 (33.1)
Coexisting conditions of interest — no. (%)‖		
Any preexisting condition	4,937 (39.6)	4,864 (38.9)
Cardiorespiratory preexisting condition	2,496 (20.0)	2,422 (19.4)
Endocrine or metabolic preexisting condition	3,200 (25.7)	3,236 (25.9)

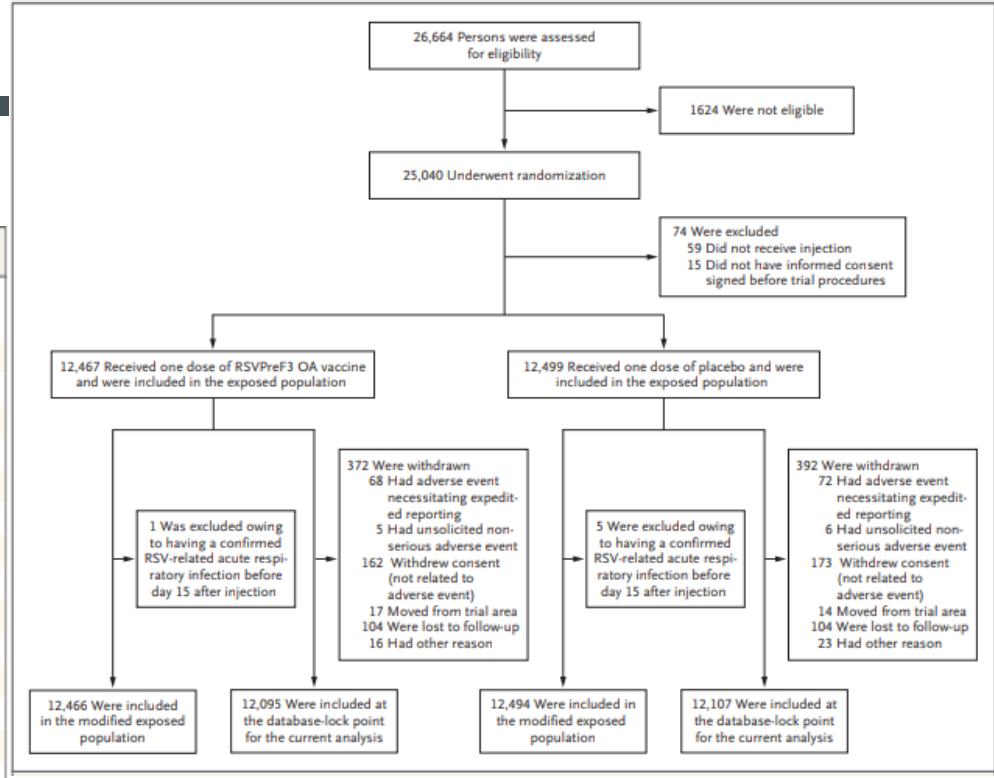
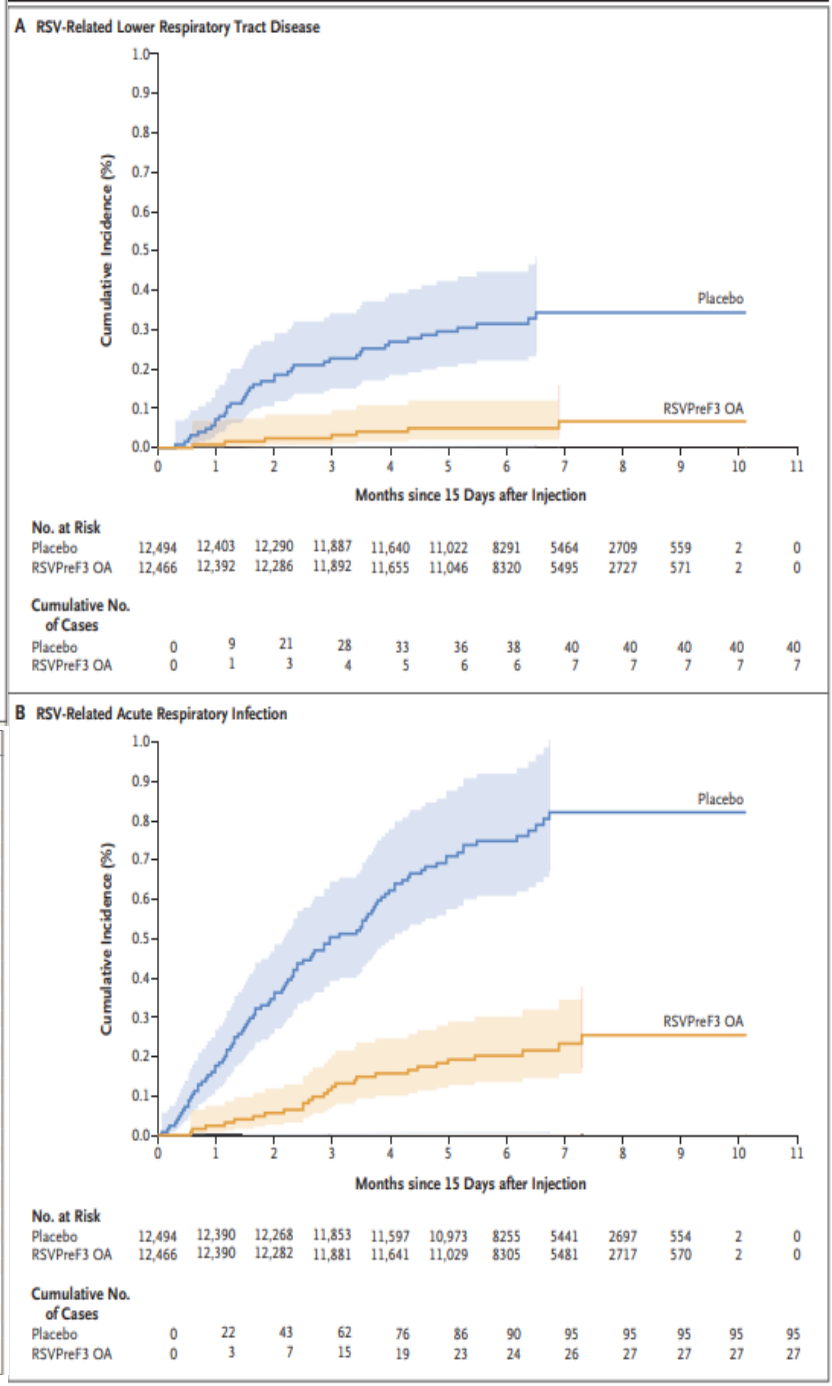


Table 3. Solicited and Unsolicited Adverse Events after Receipt of a Single Dose of the RSVPreF3 OA Vaccine or Placebo.*

Event	RSVPreF3 OA Group		Placebo Group	
	Participants	Incidence (95% CI)	Participants	Incidence (95% CI)
	no.	%	no.	%
Solicited safety population	879		878	
Solicited reactions				
Any solicited reaction	632	71.9 (68.8–74.9)	245	27.9 (25.0–31.0)
Any grade 3 solicited reaction	36	4.1 (2.9–5.6)	8	0.9 (0.4–1.8)
Solicited injection-site reactions				
Pain	535	60.9 (57.5–64.1)	81†	9.3 (7.4–11.4)
Erythema	66	7.5 (5.9–9.5)	7†	0.8 (0.3–1.6)
Swelling	48	5.5 (4.1–7.2)	5†	0.6 (0.2–1.3)
Solicited systemic reactions				
Fever‡	18	2.0 (1.2–3.2)	3	0.3 (0.1–1.0)
Headache	239	27.2 (24.3–30.3)	111	12.6 (10.5–15.0)
Fatigue	295	33.6 (30.4–36.8)	141	16.1 (13.7–18.7)
Myalgia	254	28.9 (25.9–32.0)	72	8.2 (6.5–10.2)
Arthralgia	159	18.1 (15.6–20.8)	56	6.4 (4.9–8.2)
Unsolicited adverse events				
Any unsolicited adverse event	131	14.9 (12.6–17.4)	128	14.6 (12.3–17.1)
Grade 3 unsolicited adverse event	12	1.4 (0.7–2.4)	12	1.4 (0.7–2.4)
Exposed population	12,467		12,499	
Unsolicited adverse events§				
Any adverse event	4,117	33.0 (32.2–33.9)	2,229	17.8 (17.2–18.5)
Any grade 3 adverse event	246	2.0 (1.7–2.2)	158	1.3 (1.1–1.5)
Adverse event related to vaccine or placebo	3,105	24.9 (24.1–25.7)	731	5.8 (5.4–6.3)
Grade 3 adverse event related to vaccine or placebo	112	0.9 (0.7–1.1)	25	0.2 (0.1–0.3)
Serious adverse events				
Any serious adverse event	522	4.2 (3.8–4.6)	506	4.0 (3.7–4.4)
Serious adverse event related to vaccine or placebo	10	0.1 (0.0–0.1)	7	0.1 (0.0–0.1)
Fatal serious adverse event	49	0.4 (0.3–0.5)	58	0.5 (0.4–0.6)
Fatal serious adverse event related to vaccine or placebo	3¶	—	3¶	—
Potential immune-mediated disease				
Any potential immune-mediated disease	40	0.3 (0.2–0.4)	34	0.3 (0.2–0.4)
Potential immune-mediated disease related to vaccine or placebo	7	0.1 (0.0–0.1)	5	<0.1 (0.0–0.1)



Clinical consideration: Shared clinical decision-making based on risk assessment among adults aged 60–64 years

For shared clinical decision-making recommendations there is no default.

The decision about whether or not to vaccinate an individual may be informed by:

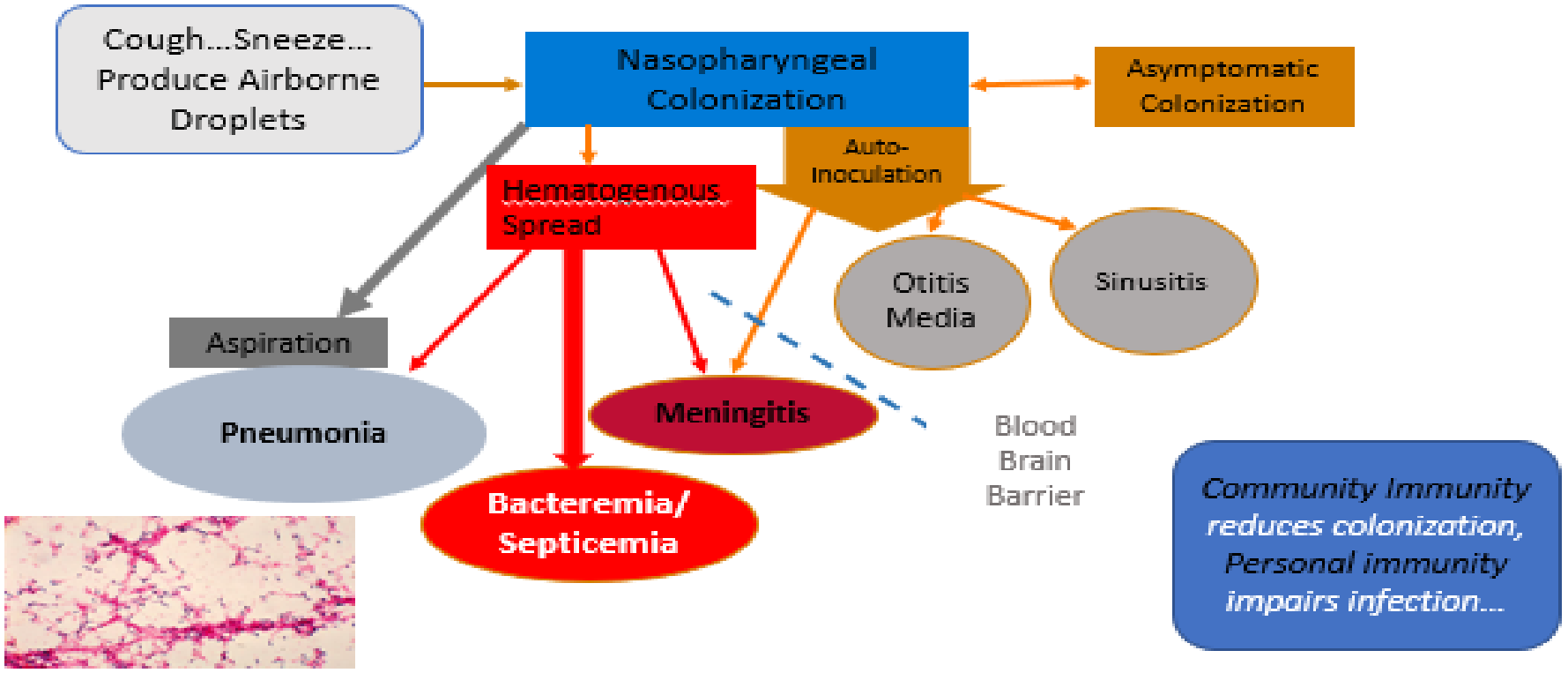
- Best available evidence of who may benefit
- An individual's characteristics, values, and preferences
- Health care provider's clinical discretion
- Characteristics of the vaccine being considered

Source: CDC. ACIP Shared Clinical Decision-Making Recommendations. Website: https://www.cdc.gov/vaccines/acip/acip-scdm-faqs.html. Last updated February 10, 2020. Accessed June 13, 2023.

RSV VACCINATION IN ADULTS 60+ AND SDM CONSIDERATIONS

- Vaccines expected to be available this fall:
  - Optimal: Immunize before RSV activity in community *but* less predictable since onset pandemic → vaccinate when available
- WHO is at highest risk: Age 60+ AND
  - Chronic lung disease — Asthma, COPD
  - Chronic heart disease — Heart failure, CAD
  - Immune compromise — Recognize that this is a heterogeneous population… High Risk but were not in clinical trials.
  - Other — Hematologic diseases, Neurologic dz, Diabetes, Kidney dz, Liver dz
  - Long term care residents
- Cost and Coverage — Not yet available…
- Coadministration — Only studied with Influenza. Reactogenicity **may** increase with multiple simultaneous vaccines
- RHH adds ??: — Occupational exposure to high risk populations [older Peds/Neo/Teacher?]

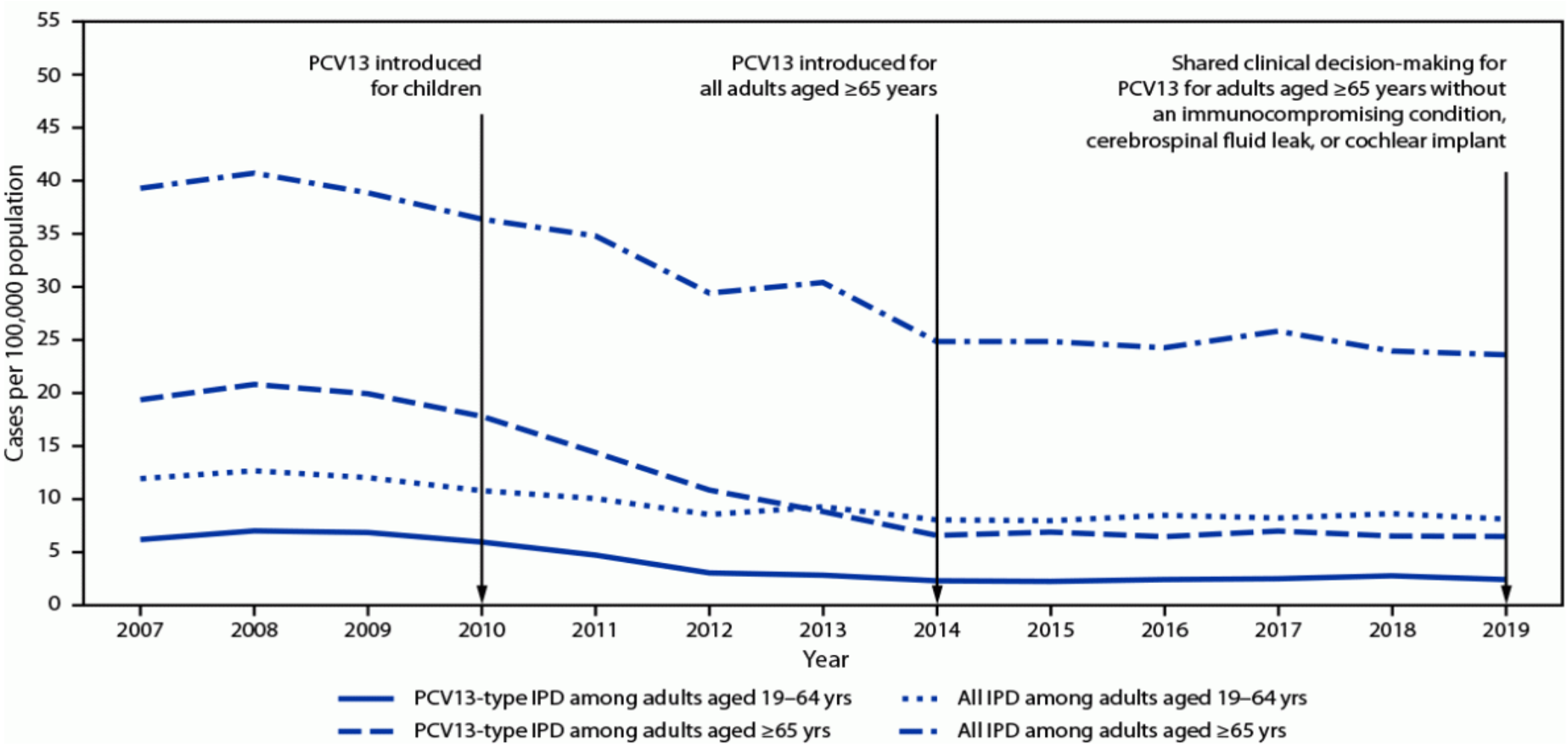
PNEUMOCOCCAL



Result: >2000 Adults 65+ die annually from invasive pneumococcal disease (IPD):
Bacteremia, sepsis, meningitis

Adapted from Henriques-Normark B, Tuomanen EI. *Cold Spring Harb Perspect Med.* 2013;3(7). pii: a010215; van der Poll T, Opal SM. *Lancet.* 2009;374(9700):1543-1556.

FIGURE. Incidence of all invasive pneumococcal disease and 13-valent pneumococcal conjugate vaccine-type* invasive pneumococcal disease among adults aged ≥19 years, by invasive pneumococcal disease type and age group — United States, 2007–2019†

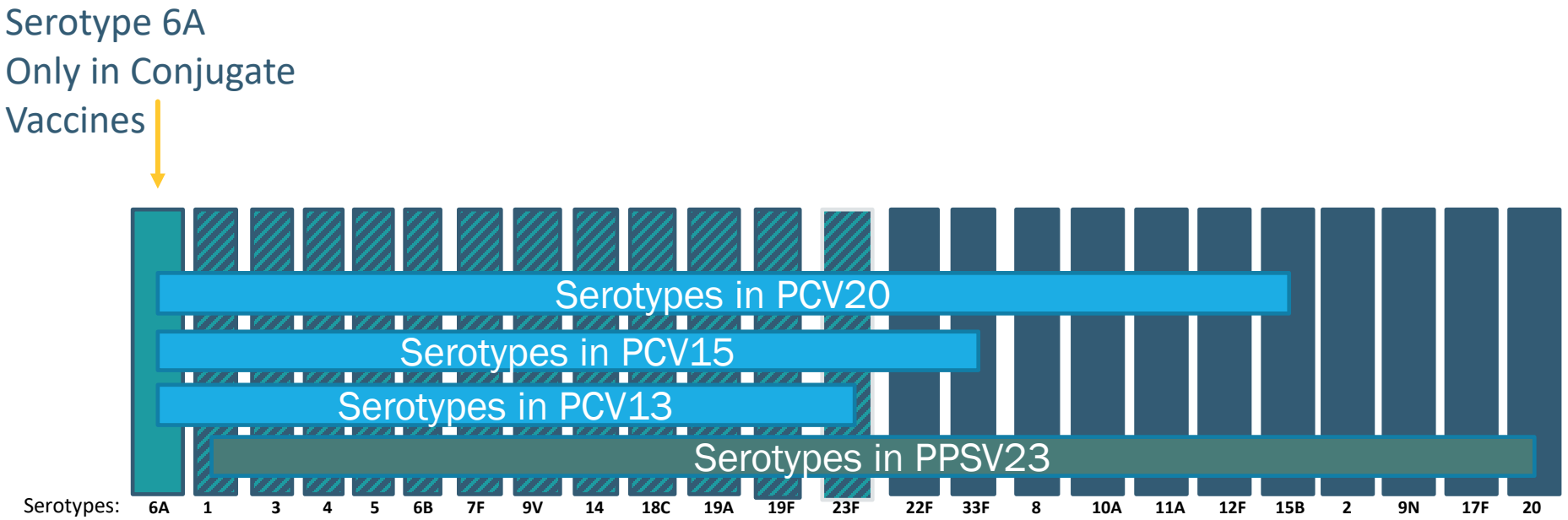


* Includes serotype 6C, which shows cross-protection from 6A antigen in PCV13 and was grouped with PCV13 serotypes for IPD incidence.

† Active Bacterial Core surveillance, 2021.

Kobayashi M, et al. *MMWR Morb Mortal Wkly Rep*. 2022;71(4):109-117

PNEUMOCOCCAL SEROTYPES IN VACCINES

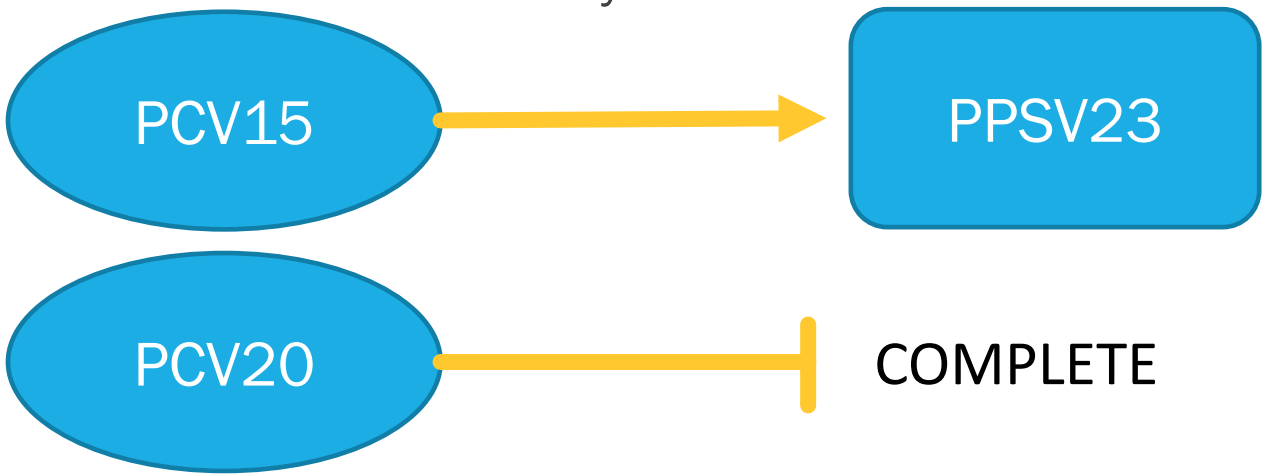


- >100 serotypes of Pneumococci identified
- Vaccines contain serotypes causing majority of pneumonia and invasive disease

https://www.cdc.gov/pneumococcal/index.html

PNEUMOCOCCAL

- Complex adult recommendations for many years
  - Those who have started Pneumococcal vaccine ‘legacy schedules’ should complete schedule
  - No data to date on multiple doses conjugate vaccines in adults…
- New Conjugate vaccines approved in 2021
  - Opportunity to simplify recommendations, improve protection
  - ‘Practice formulary’ decision: Which conjugate vaccine to stock/use
  - PPSV23 for *at least the* next few years



ADULT PNEUMOCOCCAL VACCINE: Risk Groups and Recommendations 2022 for PCV20 Use

Adults 19-64 years WITHOUT risk conditions:

***DO NOT need Pneumococcal vaccination* until they develop one or more risk medical condition or age ≥ 65 years.**

***AT RISK** MEDICAL* conditions:
Alcoholism
Cigarette Smokers
Diabetes Mellitus
Heart Disease
[Incl. CAD, CHF; NOT Isolated HTN]
Liver Disease
Lung Disease
[Incl. Asthma, COPD]

HIGHEST RISK conditions:
1. **IMMUNE COMPROMISE**:
Medications (Prednisone ≥20/d, Biologics, ...)
Cancer Treatment
Transplants [Organ, BMT, Stem Cell]
Inherited/Acquired Immune Deficiency
Sickle Cell, Splenectomy
Renal failure, Nephrotic Syndrome
2. **ANATOMIC RISKS**:
CSF Leaks, Cochlear Implants

*Adults 65+ years HIGH **RISK** due to AGE=*
Applies to ALL 65 years and older!
(Regardless of Medical Condition)

Lifetime Maximum # Adult Doses of Pneumococcal Vaccines:

PCV 13, 15 or 20	1
PPSV23^	1

Today:

Pneumococcal immunization NOT indicated *UNTIL/UNLESS develops* ***RISK condition and/or age 65+ years***

You should administer…

Pneumococcal Conjugate PCV20* Vaccine

No additional Pneumococcal Vaccination indicated.

A-I-M of this Tool:
A= ***ASK about prior Pneumococcal Conjugate PCV13 Vaccine***
If received, follow Legacy Pneumococcal Immunization schedule (attached)
I = ***Implement this tool if no prior Pneumococcal Conjugate Vaccine***
M= ***Make an impact- reduce your patient's risk for Pneumococcal disease, including Pneumonia***!!

***If PCV15 is used instead of PCV20**, it should be followed by PPSV23 in 1 year.
If PCV15 is being given prior to initiating immune compromise where maximal pneumococcal disease protection is needed ASAP, PPSV23 may be given as soon as 8 weeks after PCV15 dose.
^If completing a series begun with PCV13 before age 55, may receive up to 3 doses PPSV23

https://www.cdc.gov/mmwr/volumes/71/wr/mm7104a1.htm

R. Hopkins, MD. UAMS COM. Revised 6/1/2022

ADULT PNEUMOCOCCAL VACCINE: Risk Groups and Recommendations 2022 for PCV15 Use

Adults 19-64 years WITHOUT risk conditions:

***DO NOT need Pneumococcal vaccination* until they develop one or more risk medical condition or age ≥ 65 years.**

***AT RISK** MEDICAL* conditions:
Alcoholism
Cigarette Smokers
Diabetes Mellitus
Heart Disease
[Incl. CAD, CHF; NOT Isolated HTN]
Liver Disease
Lung Disease
[Incl. Asthma, COPD]

HIGHEST RISK conditions:
1. **IMMUNE COMPROMISE**:
Medications (Prednisone ≥20/d, Biologics, ...)
Cancer Treatment
Transplants [Organ, BMT, Stem Cell]
Inherited/Acquired Immune Deficiency
Sickle Cell, Splenectomy
Renal failure, Nephrotic Syndrome
2. **ANATOMIC RISKS**:
CSF Leaks, Cochlear Implants

*Adults 65+ years HIGH **RISK** due to AGE=*
Applies to ALL 65 years and older!
(Regardless of Medical Condition)

Lifetime Maximum # Adult Doses of Pneumococcal Vaccines:

PCV 13, 15 or 20	1
PPSV23^	1

Today: You should administer…

Pneumococcal vaccination NOT indicated *UNTIL/UNLESS develops* ***RISK condition and/or age 65+ years***

Pneumococcal Conjugate PCV15 Vaccine

If PCV15 was used: Next Pneumococcal Vaccination: ≥1 year* later

PPSV23 Vaccine Polysaccharide

No additional Pneumococcal Vaccination indicated after above doses are completed.

A-I-M of this Tool:

A= ***ASK about prior Pneumococcal Conjugate Vaccine***
If received, followed by PPSV23- Immunization complete
If received, not followed by PPSV23- complete PPSV23 ≥ 1 yr or later

I= ***Implement this tool if no prior Pneumococcal Conjugate Vaccine***

M= ***Make an impact- reduce your patient's risk for Pneumococcal disease, including Pneumonia***!!

*If PCV15 is used in an individual initiating immune compromise, PPSV23 may be given as soon as 8 weeks after PCV15 dose to reduce risk.

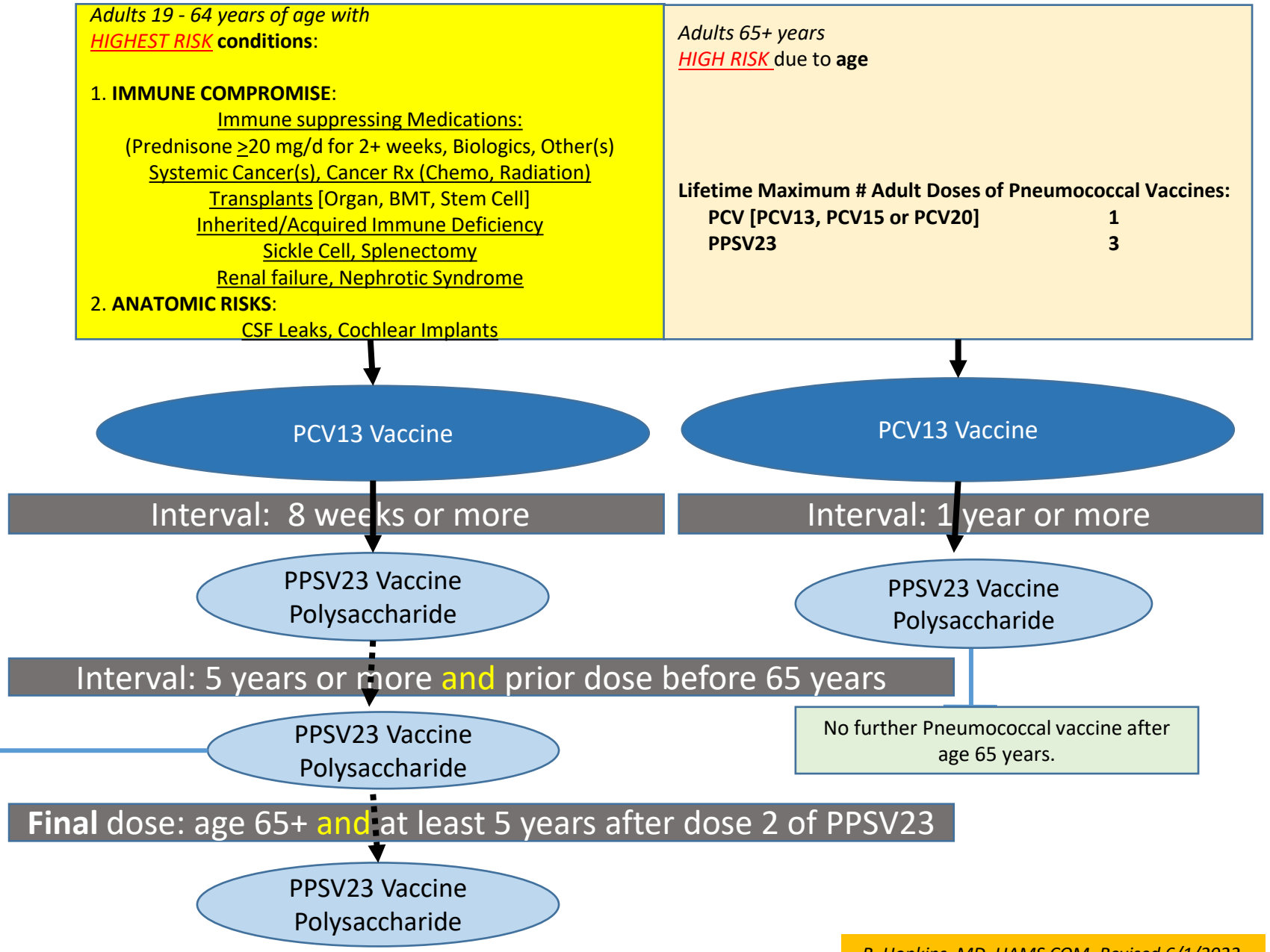
^If completing a series begun with PCV13 before age 55, may receive up to 3 doses PPSV23

https://www.cdc.gov/mmwr/volumes/71/wr/mm7104a1.htm

R. Hopkins, MD. UAMS COM. Revised 3/3/2022

LEGACY ADULT PNEUMOCOCCAL VACCINE Schedule 2022: ONLY for use in patients who have received a dose of PCV13 as an adult

Notes:
This schedule is to be used in patients who received an adult dose of Pneumococcal Conjugate Vaccine before the 2022 ACIP Pneumococcal Recommendations.

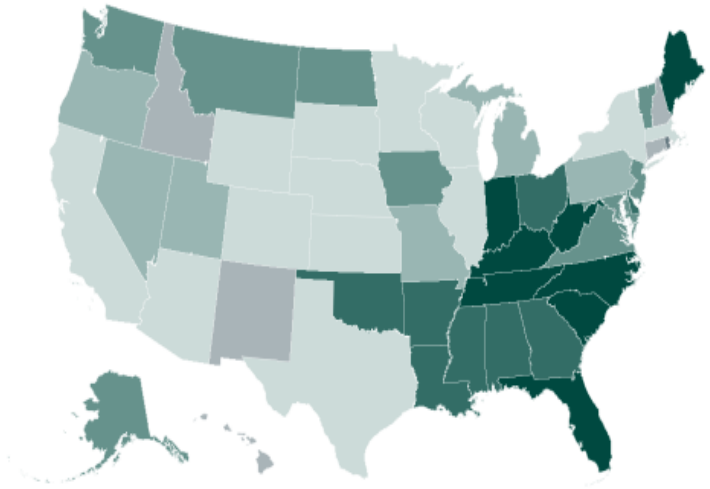


ANATOMIC RISK: If received PCV13 should receive PPSV23 8+ weeks later and 1 additional dose PPSV23 5 years later only if first PPSV23 was given prior to age 65 years.

R. Hopkins, MD. UAMS COM. Revised 6/1/2022.
Developed for educational purposes. Please Cite!

HEPATITIS B

Figure 2.3
Rates* of reported cases† of acute hepatitis B virus infection, by state or jurisdiction
United States, 2020



Cases/100,000 Population
- 0.0–0.2
- 0.3–0.4
- 0.5–0.6
- 0.7–1.2
- 1.3–3.2
- No reported cases
- Data unavailable

Color Key	Cases/100,000 Population	State or Jurisdiction
	0.0–0.2	CA, KS, MN, NE, SD, AZ, CO, IL, MA, NY, TX, WI, WY
	0.3–0.4	MO, UT, MI, NV, OR, PA
	0.5–0.6	AK, IA, MT, ND, NJ, VA, VT, WA, MD
	0.7–1.2	DE, LA, OK, GA, OH, AL, AR, MS
	1.3–3.2	NC, SC, IN, FL, TN, KY, ME, WV
	No reported cases	CT, HI, ID, NH, NM
	Data unavailable	DC, RI

* Rates per 100,000 population.

† Reported confirmed cases. For the case definition, see https://ndc.services.cdc.gov/conditions/hepatitis-b-acute/.

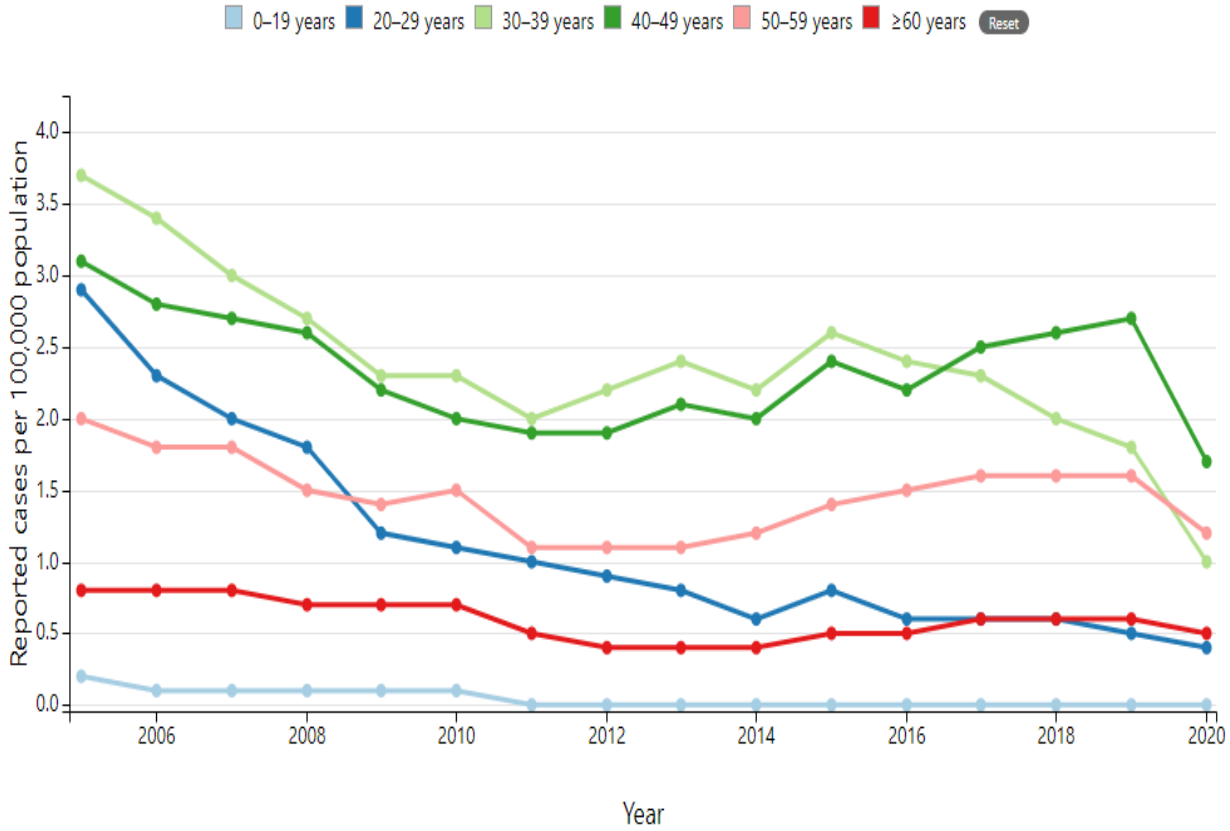
Source: CDC, National Notifiable Diseases Surveillance System.

Centers for Disease Control and Prevention. Viral Hepatitis Surveillance Report—United States, 2020. https://www.cdc.gov/hepatitis/statistics/2020surveillance/index.htm. Published September 2022.

Rates* of reported cases† of acute hepatitis B virus infection, by age group — United States, 2005-2020

Print

◀ Figure 2.3 Figure 2.5 ▶



HEPATITIS B: ADULTS < 60 YEARS

ACIP Approved UNIVERSAL HEPATITIS B Vaccination for Adults <60 years *and for those at increased risk >60 years* in November 2021

In addition to universal HBV immunization of all infants and persons <19 years

Why universal recommendation is important:

- Low uptake with risk- based recommendation
  Stigma, Time, Opportunity, Billing,…
- Opportunity to impact disease which is often acutely asymptomatic, may be chronic and reduce the risk for vaccine preventable cancer

https://www.cdc.gov/mmwr/volumes/71/wr/mm7113a1.htm

2023 CDC GUIDELINE FOR HBV SCREENING AND TESTING

Use **Triple Panel Test:**
HBsAg
anti-HBs
total anti-HBc

- **Screening** is recommended
  - once for all adults 18+ years
  - All pregnant women/every pregnancy
- **Testing** is recommended
  - Everyone with HBV infection risk with prior negative anti-HBc and have either not completed vaccination or are a vaccine nonresponder
  - Periodic testing in those with ongoing risk (Frequency= Shared decision)
  - Anyone who requests testing
- After blood is drawn for testing, those who are susceptible should be vaccinated.

BOX 4. Persons and activities, exposures, or conditions associated with an increased risk for hepatitis B virus infection — CDC testing recommendations, 2023

- Infants born to pregnant persons who are hepatitis B surface antigen positive
- Persons born in regions with hepatitis B virus (HBV) infection prevalence of ≥2%
- U.S.-born persons not vaccinated as infants whose parents were born in regions with HBV infection prevalence of ≥8%
- Injection drug use
- Incarceration in a jail, prison, or other detention setting (new recommendation)
- HIV infection
- Hepatitis C virus infection (new recommendation)
- Men who have sex with men
- Sexually transmitted infections or multiple sex partners (new recommendation)
- Household contacts of persons with known HBV infection
- Needle-sharing or sexual contacts of persons with known HBV infection
- Maintenance dialysis, including in-center or home hemodialysis and peritoneal dialysis
- Elevated alanine aminotransferase or aspartate aminotransferase levels of unknown origin
- Persons who request HBV testing (new recommendation)

https://www.cdc.gov/mmwr/volumes/72/rr/rr7201a1.htm

HEPATITIS B: ADULTS >60 YEARS

- **Behavioral and social:**
  - >1 sex partner in 6 months
  - People seeking STD evaluation or treatment
  - Household contacts and sexual partners of HBsAg+ people
  - MSM
  - IVDU [current or recent]
  - Incarcerated persons
- **Occupational**
  - Health care, public safety workers, staff working with developmentally disabled
- **Medical**
  - Persons with Diabetes mellitus at MD discretion
  - Persons with (any) chronic liver disease
    [incl. HCV, cirrhosis, NASH/fatty liver, alcoholic liver dz, autoimmune hepatitis, ^ transaminases]
  - Persons living with HIV
  - Dialysis patients (Hemo- and Peritoneal) and ESRD patients pre-dialysis
- **International Travel:** destination with endemic HBV (community prevalence $\geq$ 2%)
- **Adults 60+ without risk factors MAY be vaccinated to prevent** hepatitis B

https://www.cdc.gov/mmwr/volumes/71/wr/mm7113a1.htm

ADULT HEPATITIS VACCINES, SCHEDULES

Vaccine Product	Protects Against	Adjuvant	Indications	Schedule
Havrix	Hepatitis A	Aluminum	1-18 y, 19+ y	0, 6-12 mo.
Vaqta	Hepatitis A	Aluminum	1-18 y, 19+ y	0, 6-18 mo.
Twinrix	Hepatitis A + B	Aluminum	18+ only*	Standard: 0, 1 mo., 6 mo. Accelerated: 0, 7d., 21-30 d., 12 mo.
Engerix-B	Hepatitis B	Aluminum	Birth-19, 20+	Standard: 0, 1 mo., 6 mo. *Various alternative schedules OK…*
Recombivax HB	Hepatitis B	Aluminum	Birth-19, 20+	
Recombivax HB Dialysis formulation	Hepatitis B	Aluminum	IS, ESRD	Standard: 0, 1 mo., 6 mo. Check Titer
PreHevbrio	Hepatitis B	Aluminum	18+ only*	0, 1 mo., 6 mo.
Heplisav B	Hepatitis B	TLR9 [CPG 1018]	18+ only*	0, 1 mo.

- All are inactivated, administered IM
- Build universal HBV immunization into preventive care processes

HTTPS://WWW.CDC.GOV/MMWR/VOLUMES/69/RR/RR6905A1.HTM
HTTPS://WWW.CDC.GOV/MMWR/VOLUMES/67/RR/RR6701A1.HTM
HTTPS://WWW.CDC.GOV/MMWR/VOLUMES/67/WR/MM6715A5.HTM
HTTPS://WWW.CDC.GOV/MMWR/VOLUMES/67/RR/RR6701A1.HTM

* Not ESRD, Pregnancy AT PRESENT

CHALLENGES IN HEPATITIS B VACCINATION

- Response to standard Hepatitis B vaccines lower in patients with:
  - Obesity
  - Diabetes Mellitus [more so with longer duration of disease]
  - Renal failure
  - Increasing age
  - Immune compromising conditions
- Immune Senescence: Vaccine response highest in children, decline with age
- ACIP does not recommend a specific vaccine product for HBV immunization

  except immune compromise, hemodialysis [high dose/dialysis-formulation]
- 'Standard vaccines' v. TLR-Adjuvanted
  - STD: 3 doses at 0, 1, 6 mo
  - Renal/IC Dose: 3 doses at 0,1, 6 mo Titers…
  - TLR-Adjuvanted: 2 doses at 0, 1 mo

https://www.cdc.gov/mmwr/volumes/67/rr/rr6701a1.htm

VACCINATION IN 2023

WE ARE IN A CHALLENGING PLACE…
RE: IMMUNIZATION

- Active anti-vaccine/anti-science messages on SOME and in media
- Ongoing (and increasing) vaccine hesitance in patients/families
- Vaccine information and misinformation is not clearly distinguished
- Not all providers use ‘best practices’ to get patients vaccinated
- Not all patients have coverage/not all plans cover all vaccines equally
- Access to a vaccinating provider is variable
- There is not ONE easily-accessible, comprehensive, permanent vaccine record

Some, but not all, of these challenges are new…

MAKING VACCINATION RECOMMENDATIONS

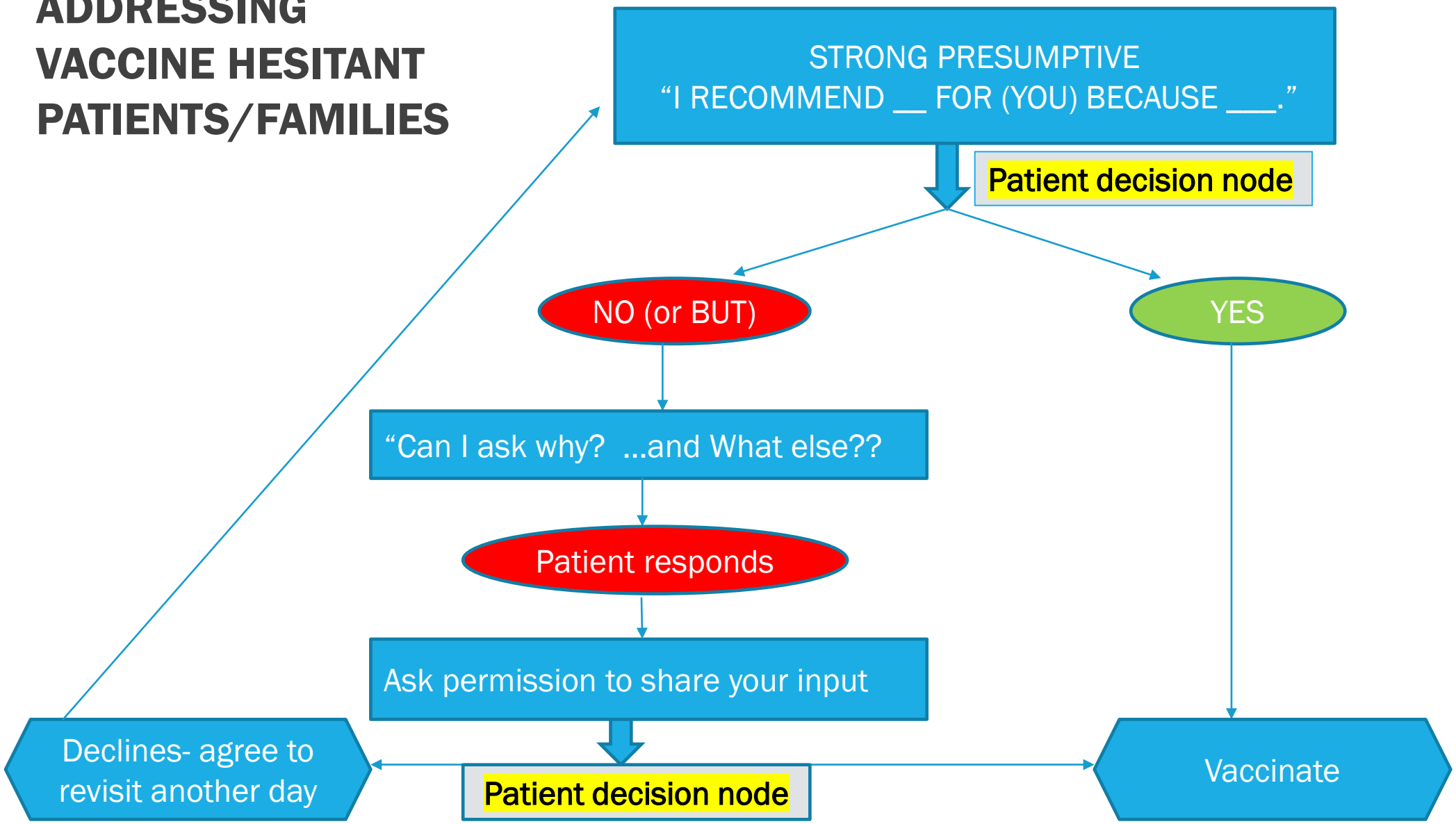
- People do not make decisions ‘in a vacuum’
- WE think of them as a core preventive strategy against many diseases, resulting in countless savings *but not all patients and families have the same construct*.
  - Immune response to vaccine depends on humans (acceptance and substrate to respond)
  - Booster doses may be important to sustain benefits
  - Immune suppressed may remain at higher risk despite vaccination
  - Changes in recommendations need to be explained clearly and in ‘common’ language
- Many individuals do not understand their own personal risk
- We have no choice but to see the challenge posed by widespread anti-science [anti-vaccine] misinformation

https://www.ncbi.nlm.nih.gov/books/NBK220057/
https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2784592
https://www.sciencedirect.com/science/article/pii/S1286457921000332

IMMUNIZATION COMMUNICATION

- Vaccination is a TEAM SPORT
- STRONG, PRESUMPTIVE provider recommendation
  - Improves vaccine uptake
  - Greatest impact when TRUST has been established
- Vaccine hesitancy falls along a spectrum
  - Most accept vaccines
  - Many have questions and concerns
  - Few are anti-science/anti-vaccine

ADDRESSING VACCINE HESITANT PATIENTS/FAMILIES



PATH TO IMMUNIZATION COMMUNICATION: ADDRESSING THE HESITANT

- **P**repare yourself: Open, empathetic [Words/Voice/Expressions]
- **A**pproach patient: Can we talk a moment about you (your concerns about) and --- vaccine?
- **T**alk the talk: *Culturally humble*

  Brief (positive) messages- disease risk, vaccine safety

  Identify misinformation while avoiding rebuttals

  Acknowledge knowledge gaps

  Remember that innumeracy is common

- **H**umanize: 'Put a face' on your recommendation (says: YOU are important to ME!)
- ***E**mbrace the long game*: Ideal to vaccinate today but *not a loss* <u>if</u> agree to revisit at future time <u>and</u> revisit conversation as planned

  (E is silent…LOL)

VACCINATION IN PRACTICE: INFLATION REDUCTION ACT 2022

- MOST adult vaccines given as ACIP recommends = covered by all payers
- Challenges:
  - ACIP recommendation not yet 'Published' in MMWR
    - Director Walensky to 'published' CDC approvals on Website. Hope this will continue…
  - 'Shared decision making' vaccines
    - Ongoing challenge.. Communicate with payers. Clear document medical necessity, appeal templates.
  - Shingles and Tdap vaccines in Medicare recipients
    - IRA provides 1st dollar coverage for all Medicare Part D vaccines in 'in network' pharmacies
  - Shingles and vaccines recommended based on medical condition in Medicaid recipients
    - CMS is still working on rule making for Medicaid programs… Stay tuned!!!

THANK YOU FOR YOUR TIME AND ATTENTION