VACCINES NEW AND OLD: PREVENTING RESPIRATORY INFECTIONS ACROSS THE LIFESPAN

MODERATOR

LISA MARIE SERRANO - EFTYCHIOU, PHARMD

NHPA PRESIDENT, PHARMACY MANAGER
CITY OF HOPE, DEPARTMENT OF PHARMACY SERVICES
LOS ANGELES, CALIFORNIA

SPEAKER

KERI HURLEY, PHARMD, MPH, BCACP, APH

HEALTH SCIENCES ASSOCIATE CLINICAL PROFESSOR
DEPARTMENT OF CLINICAL PHARMACY PRACTICE
IRVINE, CALIFORNIA

Feb. 27

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UAN: 0060-9999-23-078-L06-P

Welcome

Lisa Serrano-Eftychiou
Pharmacy Manager, NHPA President-Elect
City of Hope, Department of Pharmacy Services
Los Angeles, CA

Housekeeping

- All participant microphones will be muted, but please feel free to type your question into the Q & A box for the panelists to address during our Q & A session at the end.
- Please fill out the short post-webinar survey that will be emailed out after the event and also shown as a QR code at the end.
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- Instructions to claim CE credits will only be sent to participants who are in attendance for the full hour (no less than 50 minutes).
- UAN: 0060-9999-23-078-L06-P

Disclosure

None of the planners for this educational activity have relevant financial relationship(s) to disclose with ineligible companies whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

UCI School of Pharmacy & Pharmaceutical Sciences

Vaccines New and Old: Preventing Respiratory Infections Across the Lifespan

Keri Hurley-Kim, PharmD, MPH, BCACP, APh
Associate Clinical Professor, Department of Clinical Pharmacy Practice
University of California, Irvine
School of Pharmacy and Pharmaceutical Sciences
k.hurley@uci.edu

Learning Objectives

Upon completion of this activity, participants should be better able to:

1. Discuss historical and ongoing health and vaccine inequities related to influenza, COVID-19 and RSV.
2. Review the evidence behind updated CDC ACIP recommendations for use of influenza, COVID-19 and RSV vaccines.
3. Discuss how to apply current CDC ACIP recommendations to patient-specific decision-making with consideration for clinical, social, and equity factors.
4. Describe patient education related to vaccines and the factors underlying individual immunization recommendations.

CE question #1

HW is a 41-year-old female patient with a severe allergy (anaphylaxis) to eggs, and no other medical history. She has always been told she should not receive influenza vaccine. Which of the following is correct based on current CDC ACIP recommendations?

a) She should not receive any currently available influenza vaccine
b) She should only receive a non-egg-based formulation
c) She should only receive influenza vaccination in a setting where a provider is experienced in managing severe allergic reactions
d) She should receive any formulation that is appropriate for her age in any setting

CE question #2

Updated 2023-2024 COVID-19 vaccines became available in the U.S. in September. Recent vaccine uptake data indicate that: **[Select all that apply]**

a) White, non-Hispanic individuals have received vaccination at rates up to 3x that of minoritized groups
b) Adults of all racial/ethnic groups are receiving vaccination at about the same rate
c) Less than 20% of adults have received a dose
d) A majority of adults have received a dose

CE question #3

Studies have demonstrated that RSV immunizations can reduce the risk of severe RSV-related illness in:

a) Adults age ≥60yo
b) Infants
c) Pregnant women
d) A and B only

CE question #4

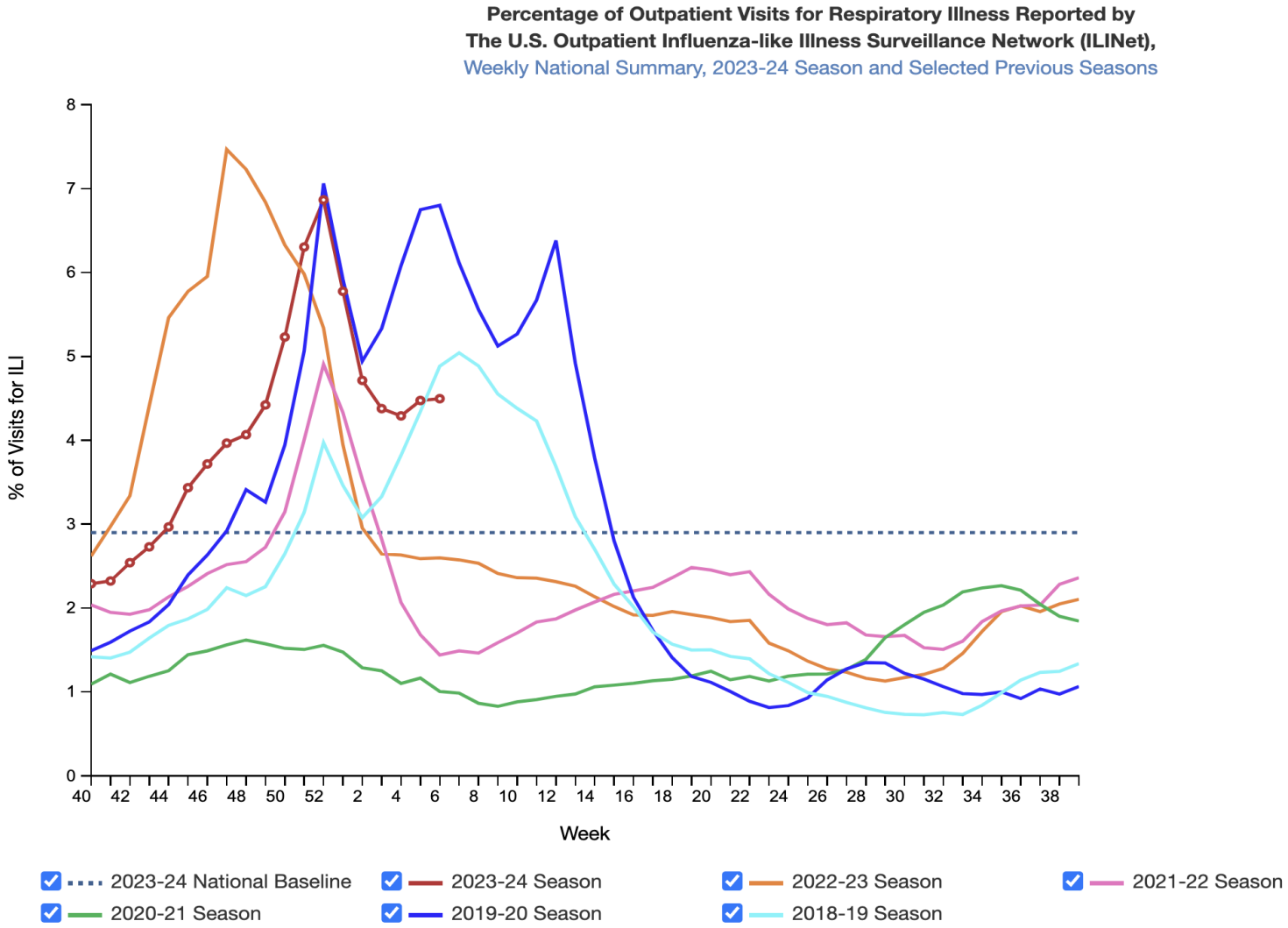
Which of the following best describes the patterns of disparities in RSV infection among young children in the U.S.?

a) Historical disparities have mostly impacted children of all minoritized groups equally
b) Incidence was higher in Black and Hispanic children during the last two RSV seasons compared to white children
c) Socioeconomic status is not an important factor in RSV incidence
d) American Indian and Alaska Native children have historically been at a lower risk of severe RSV infection

Influenza

Epidemiology

- Irregular seasonal peaks since 2019-2020 season related to COVID-19 pandemic
  - Trend may be normalizing
- H1N1 predominating this season



CDC. Weekly US Influenza Surveillance Report. https://www.cdc.gov/flu/weekly/index.htm#ILINet

Influenza

Vaccine composition 2023-2024

- All formulations are quadrivalent and contain:
  - an A/Victoria/4897/2022 (H1N1)pdm09-like virus*
  - an A/Darwin/9/2021 (H3N2)-like virus
  - a B/Austria/1359417/2021 (B/Victoria lineage)-like virus
  - a B/Phuket/3073/2013 (B/Yamagata lineage)-like virus

Breaking news: B/Yamagata antigen recommended not to be included in 2024-2025 formulations

*Cell- or recombinant formulations include an A/Wisonsin/67/2022 (H1N1)pdm09-like virus

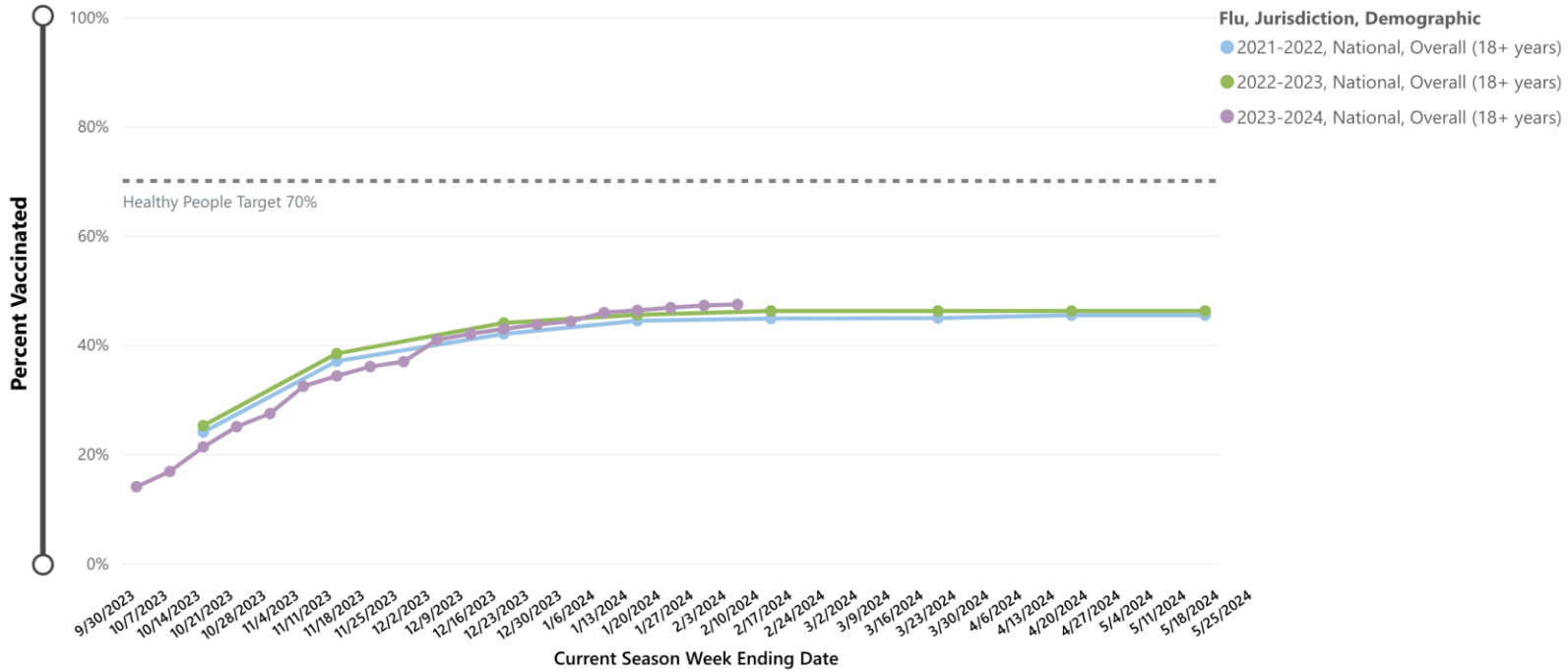
CDC. MMWR Recomm Rep 2023;72(No. RR-2):1–25

Influenza

Vaccine coverage

- Older adult age groups and younger pediatric age groups have higher vaccination rates
- Enduring disparities exist among Black and Hispanic adults

Figure 4A. Influenza Vaccination Coverage, by Selected Demographics, 2023-24 and Jurisdiction
Adults 18 years and Older, United States,*‡†±
Data Source: National Immunization Survey-Adult COVID Module

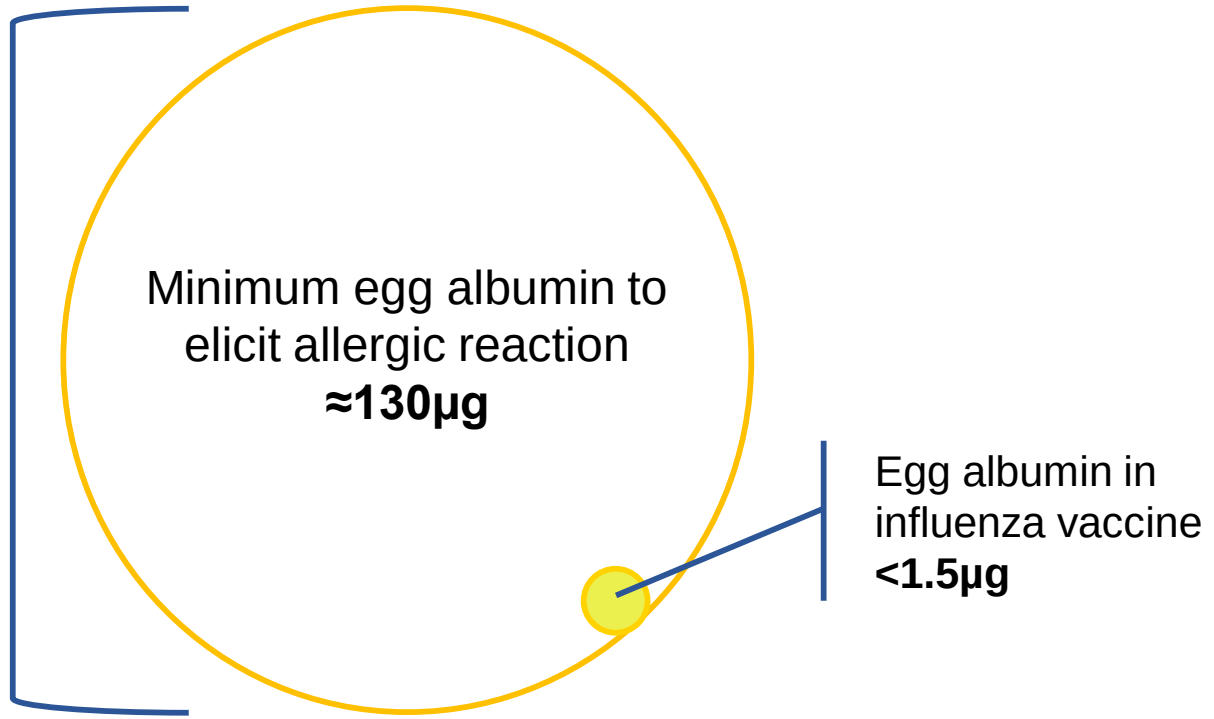


CDC. Weekly Flu Vaccination Dashboard. https://www.cdc.gov/flu/fluvaxview/dashboard/vaccination-dashboard.html

Influenza

ACIP vaccine recommendation updates

Egg-allergic individuals can receive **any age-appropriate flu vaccine** in **any setting** where it is normally offered, from **any vaccinating provider**



MMWR Recomm Rep 2023;72(No. RR-2):1–25. McNeil MM et al, J Allergy Clin Immunol 2016 Mar;137(3):868-78; Turner PG et al, BMJ. 2015 Dec 8;351:h6291

Influenza

ACIP vaccine recommendation updates

- Ideal time to vaccinate is **Sept-Oct** for most individuals
  - Exceptions: children who need 2 doses and pregnant persons in 3rd trimester should receive a dose as soon as vaccine is available
  - Consider early vaccination for individuals who may not be reachable during Sept/Oct
- Continue offering vaccine until supply is expired/exhausted

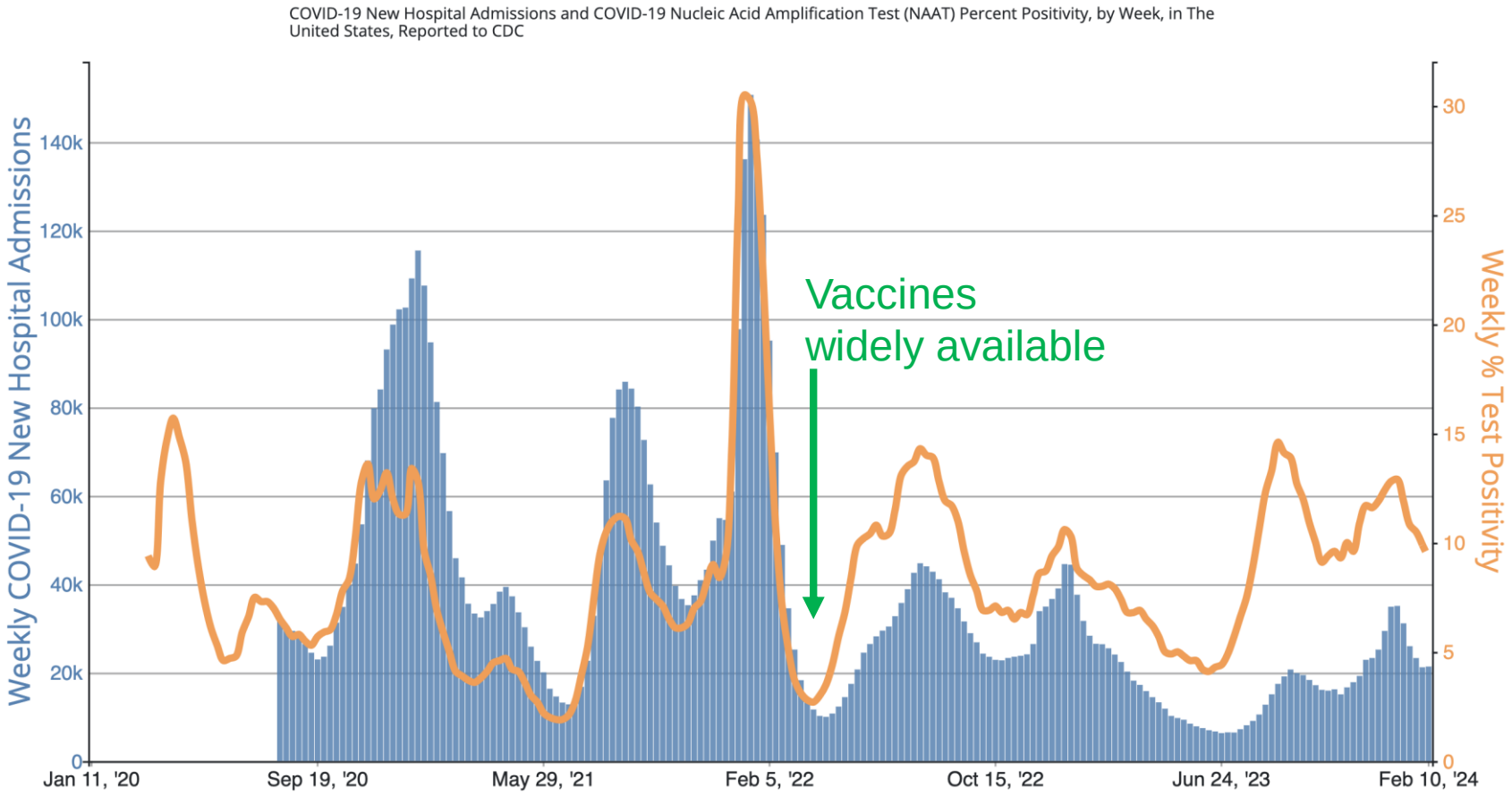
July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	June
▲	▲	★	★	●	●	●	●	●	●	●	●

CDC. MMWR Recomm Rep 2023;72(No. RR-2):1–25

COVID-19

Epidemiology

Since Spring 2022, vaccines have been the primary driver of reduced COVID-19 morbidity and mortality



https://covid.cdc.gov/covid-data-tracker/#datatracker-home

COVID-19

Vaccine effectiveness

- Updated data
  1. **Mortality rate in unvaccinated adults ≥65yo was 7-16x** that in bivalent vaccine recipients between Sept 2022-Mar 2023.
  2. Real world data shows **vaccine efficacy up to 80%** (95%CI 0.42-0.96) in preventing laboratory-confirmed ED and urgent care visits among **children 6mo-5yo.**
  3. Vaccine efficacy in preventing hospitalization in adults with and without immunocompromise declined within 60-120 days after vaccination, however **protection was significantly more durable for critical illness.**

MMWR Morb Mortal Wkly Rep 2023;72:667–669.
MMWR Morb Mortal Wkly Rep 2023;72:886–892.
MMWR Morb Mortal Wkly Rep 2023;72:579–588.

COVID-19

Vaccine safety

- Updated data
  - No new post-EUA safety signals identified for Novavax formulation in age ≥12yo
    - Analysis was limited by the small number of doses administered nationwide
  - No new post-EUA safety signals identified for bivalent mRNA booster in children 5-11yo
    - Based on nearly 1 million doses administered in this age group

MMWR Morb Mortal Wkly Rep 2023;72:850–851.
MMWR Morb Mortal Wkly Rep 2023;72:39–43.

COVID-19

Vaccines

- UPDATED 2023-2024 monovalent vaccines
  - **Omicron variant XBB.1.5**

  - Pfizer (Comirnaty) mRNA vaccine – FDA approved
  - Moderna (Spikevax) mRNA vaccine – FDA approved
  - **NEW:** Novavax protein subunit, adjuvanted vaccine - FDA EUA

MMWR Morb Mortal Wkly Rep 2023;72:1140–1146

COVID-19

Fall 2023 ACIP recommendations

Most individuals should receive one dose of an updated XBB.1.5 mRNA vaccine or protein subunit vaccine at least 8 weeks after the most recent previous dose

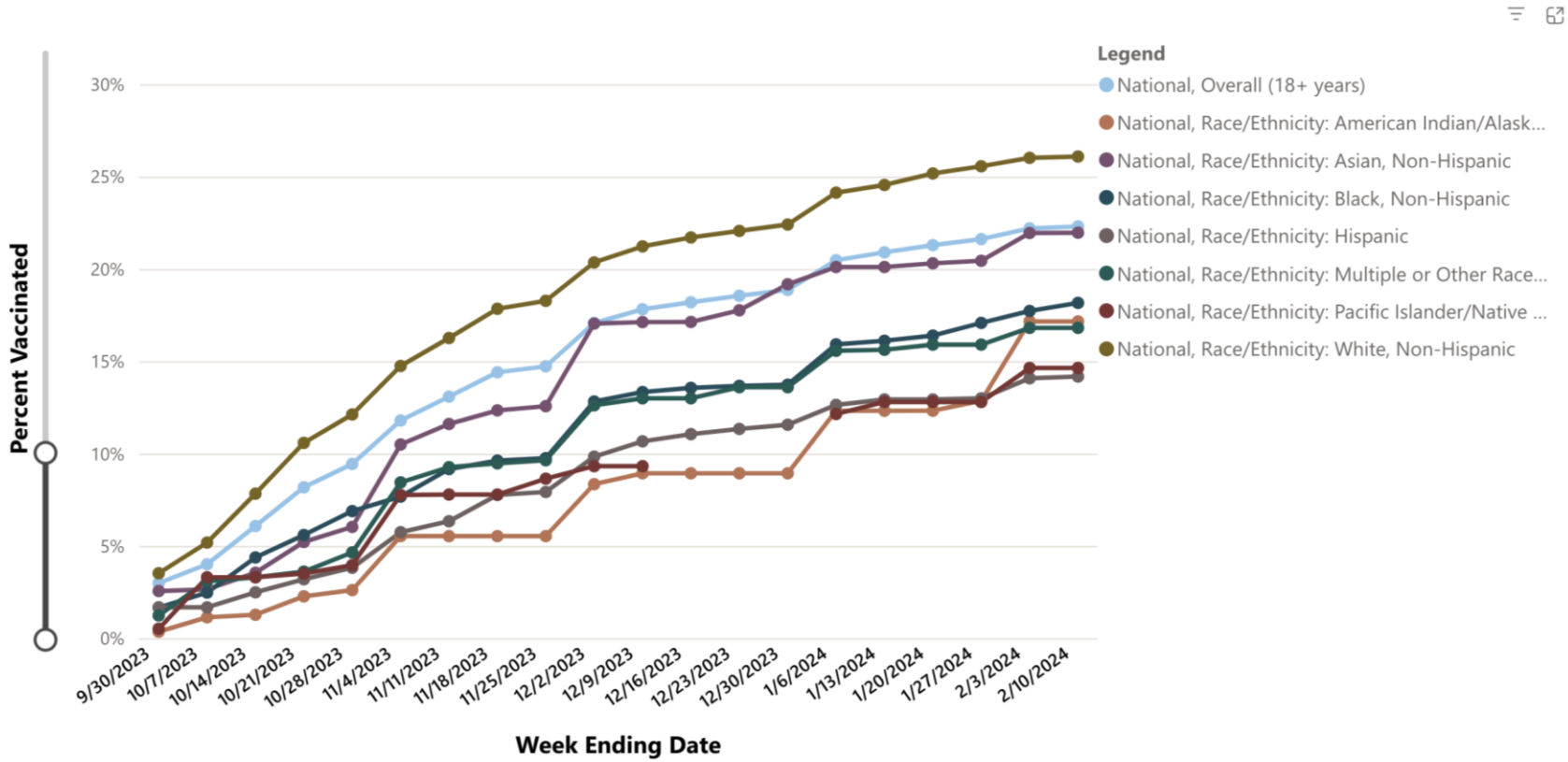
- **Exceptions:**
  - Vaccine naïve or incompletely vaccinated children 6mo-4yo should receive/complete a primary series (2-3 doses) of updated mRNA vaccine
  - Vaccine naïve individuals ≥12yo receiving protein subunit vaccine should receive a 2-dose series
  - Immunocompromised individuals may require additional doses

CDC. MMWR Recomm Rep 2023;72(No. RR-2):1–25

COVID-19

Vaccination rates

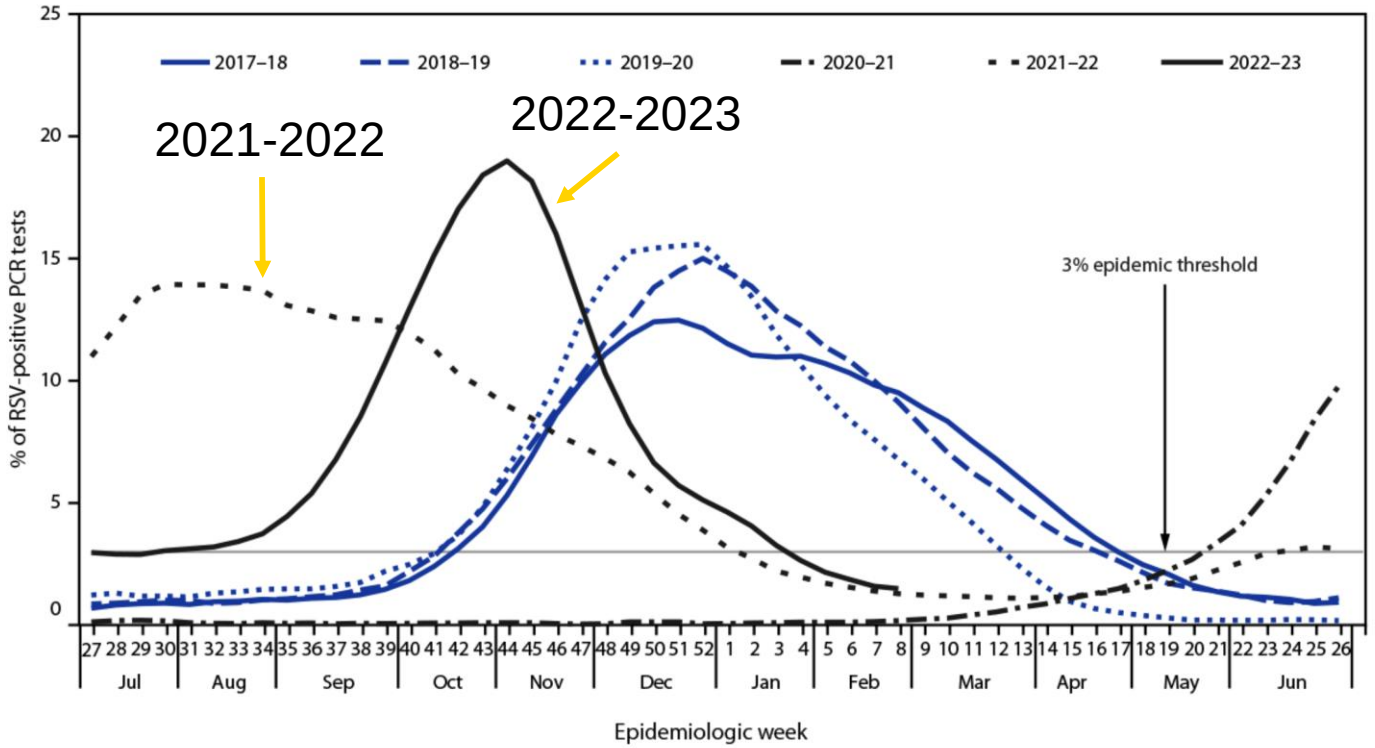
Figure 3A. Cumulative Percentage of Adults 18 Years and Older Vaccinated with the Updated 2023-24 COVID-19 Vaccine*,†,‡,±
Data Source: National Immunization Survey–Adult COVID Module



https://www.cdc.gov/vaccines/imz-managers/coverage/covidvaxview/interactive/adult-coverage-vaccination.html

Respiratory syncytial virus

FIGURE 1. Percentage* of polymerase chain reaction test results positive for respiratory syncytial virus, by epidemiologic week — National Respiratory and Enteric Virus Surveillance System, United States, July 2017–February 2023



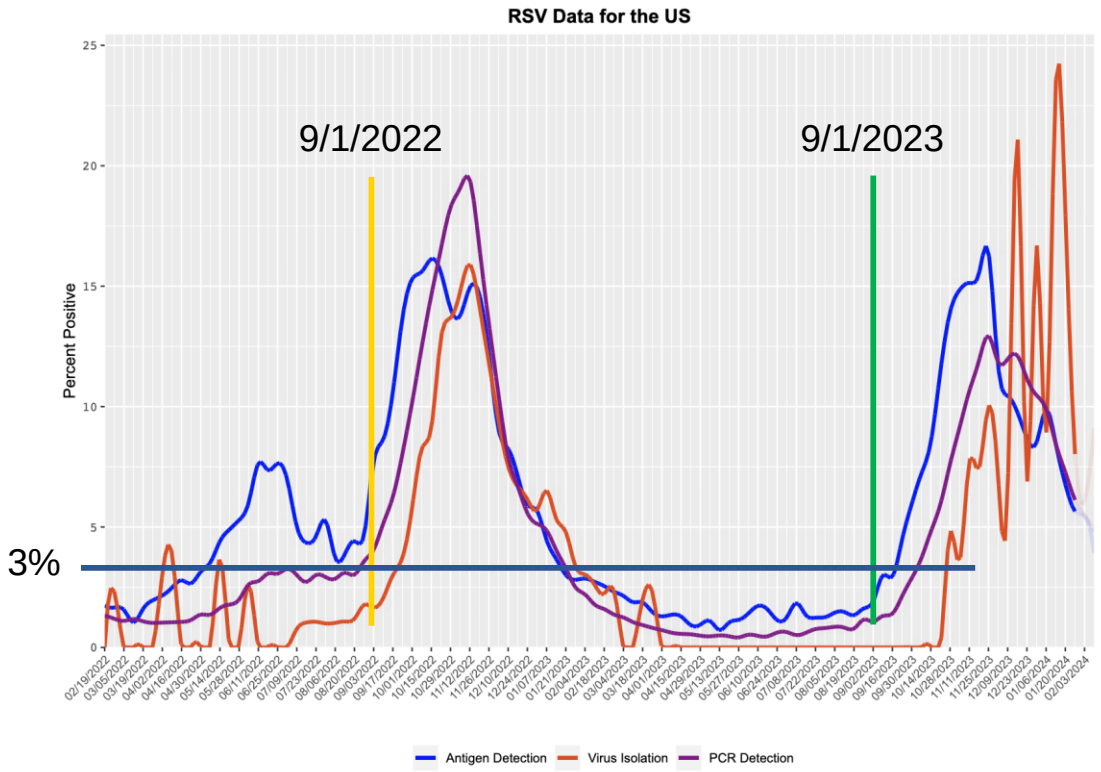
- Pre-pandemic seasonality more closely aligned to typical flu season
- Groups most at risk for hospitalization and mortality are **children <5 years and adults ≥65 years**

MMWR Morb Mortal Wkly Rep 2023;72:355–361.
CDC. RSV National Trends. www.cdc.gov/surveillance/nrevss/rsv/natl-trend.html.

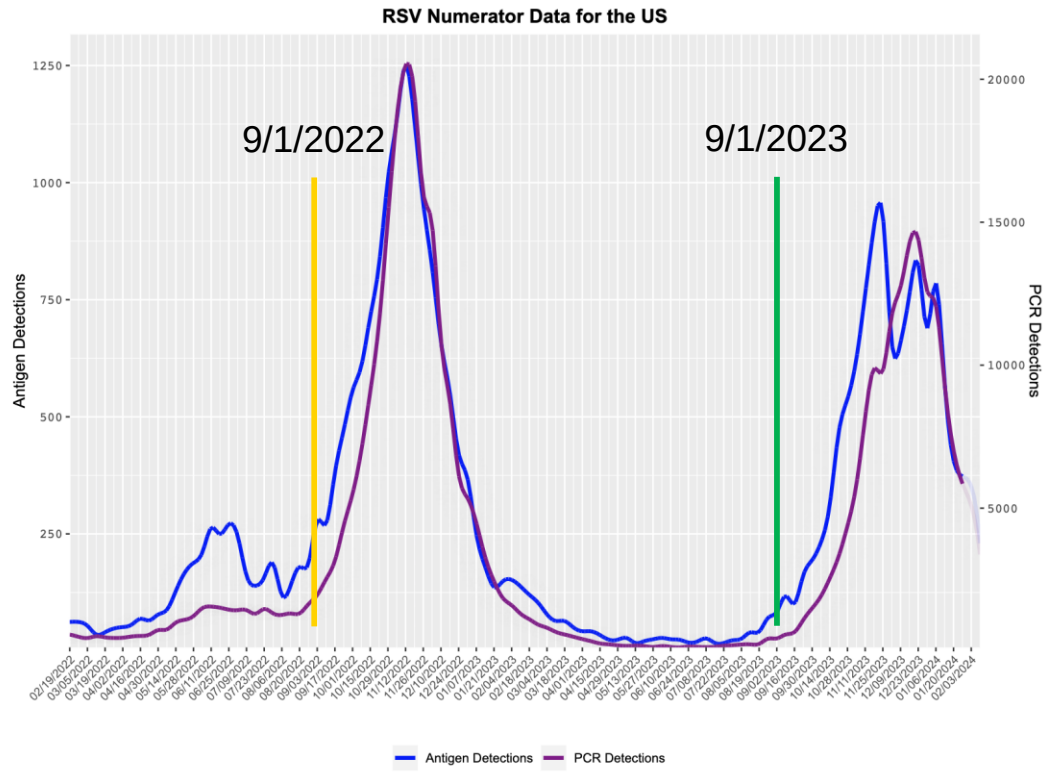
Respiratory syncytial virus

Respiratory Syncytial Virus (RSV)

Percent Positive



Detections



CDC. RSV National Trends. www.cdc.gov/surveillance/nrevss/rsv/natl-trend.html.

Respiratory syncytial virus disparities

Sangare, et al. 2006. Hospitalization for respiratory syncytial virus among California infants: Disparities related to race, insurance, and geography

Table. Race/ethnic specific RSV infant hospitalization rates by payer source, California 1999-2003

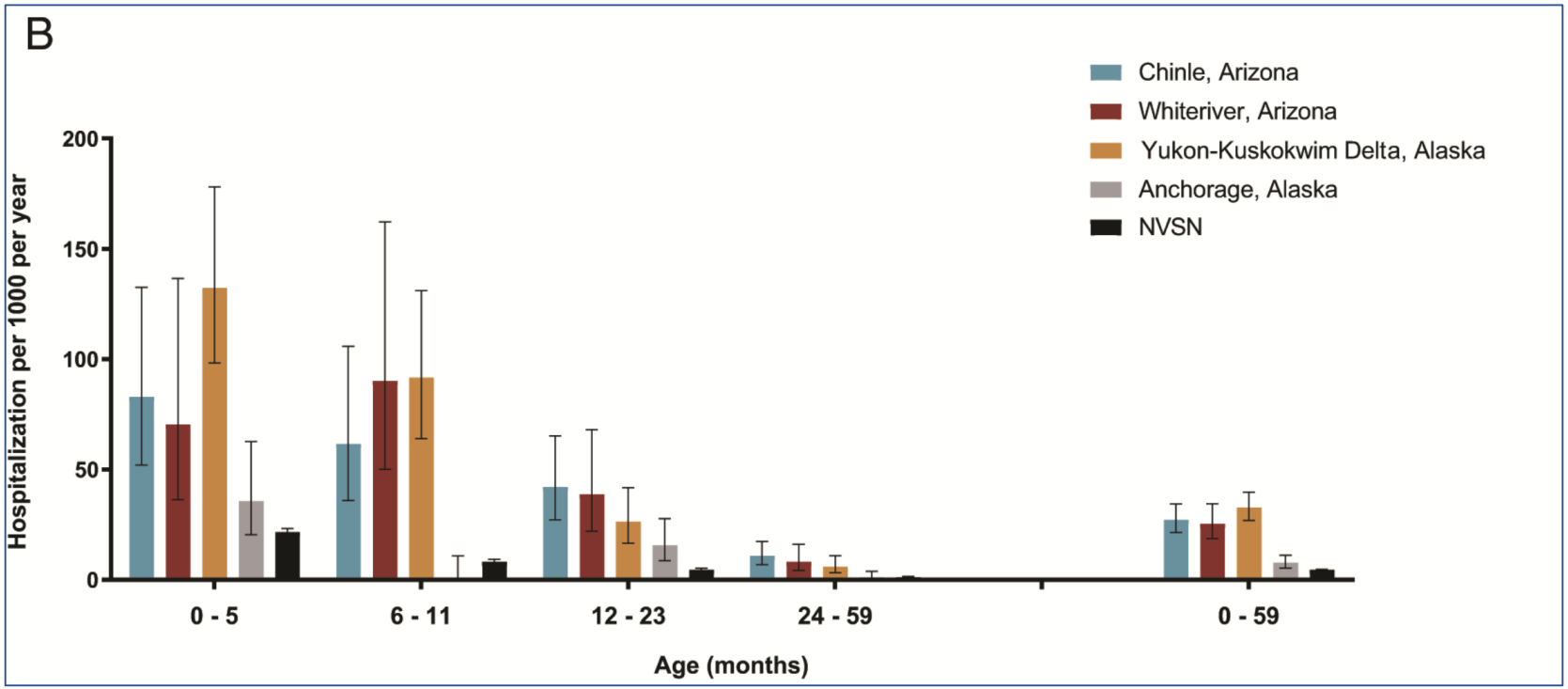
Race/ethnicity	MediCal RSV infant hospitalization rate	Lower 95% CI	Upper 95% CI	Non-MediCal RSV infant hospitalization rate	Lower 95% CI	Upper 95% CI
Non-Hispanic white	34.9*	34.0	35.8	11.9	11.7	12.2
African-American	27.9*	26.7	29.0	12.1	11.3	12.8
American Indian/Alaska Native	12.2**	9.5	15.4	8.0	5.9	10.7
Asian/Pacific Islander	12.5*	11.7	13.4	5.6	5.3	5.9
Hispanic	21.8*	21.5	22.2	13.7	13.4	14.1
Total	24.3*	24.0	24.5	12.0	11.8	12.1

"Infants enrolled in MediCal...had a relative risk of 2.03 (95% CI, 1.99 to 2.06) compared with non-MediCal payers..."

J Pediatr. 2006. 149(3):373-77

Respiratory syncytial virus disparities

Atwell, et al. 2023. RSV Among American Indian and Alaska Native Children: 2019 to 2020.



Age-based hospitalizations found to be 1.7-7.1 times higher than national NVSN rates

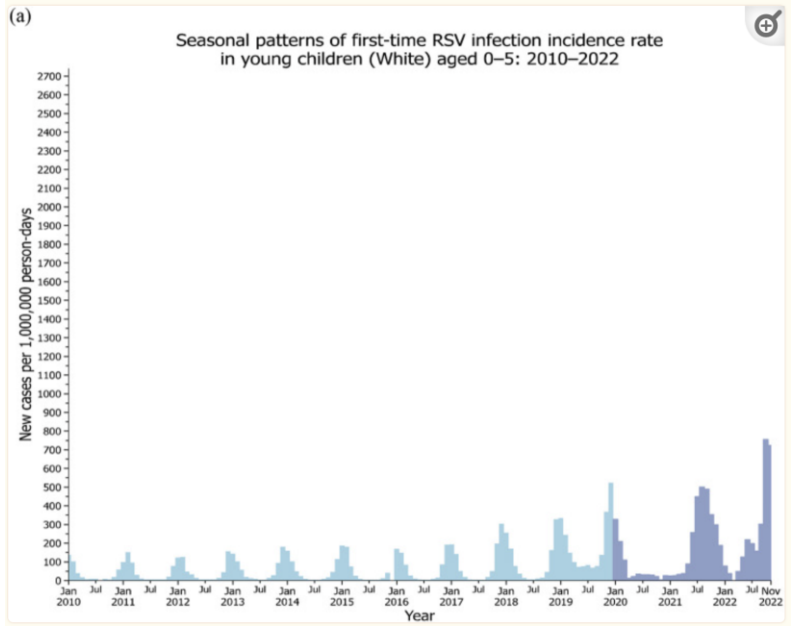
Pediatrics. 2023. 152(2):e2022060435

Respiratory syncytial virus disparities

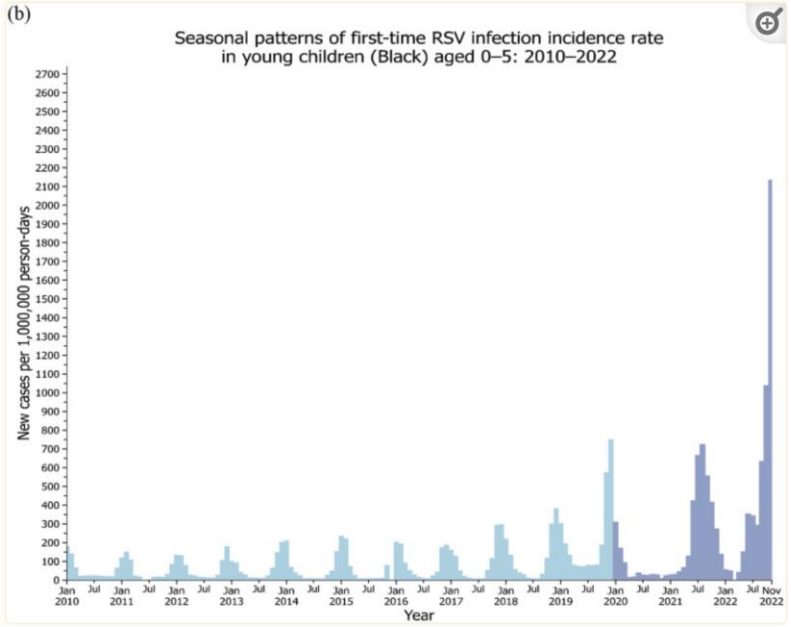
Preprint

Wang, et al. 2022. Disruption in seasonality, patient characteristics and disparities of respiratory syncytial virus infection among young children in the US during and before the COVID-19 pandemic: 2010-2022

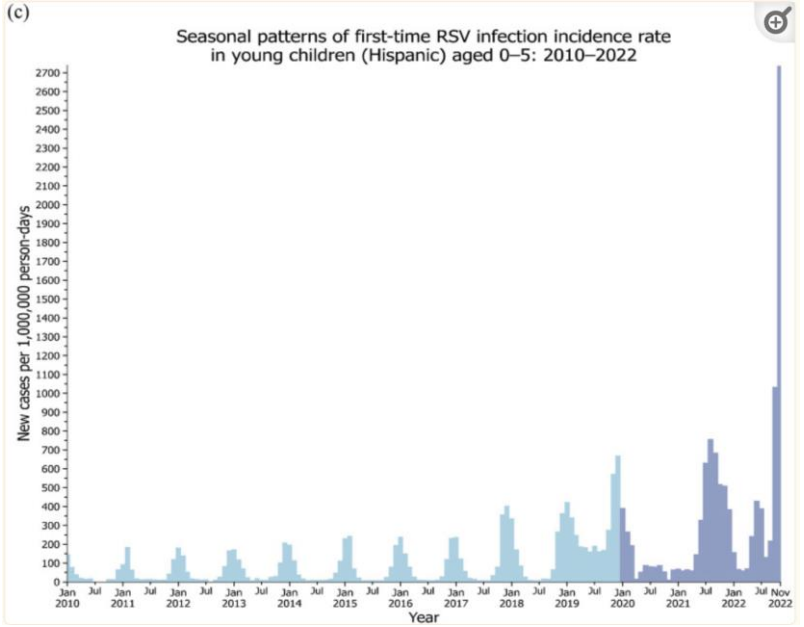
Age 0-5, white



Age 0-5, Black



Age 0-5, Hispanic



Wang, et al. PMCID Version 1. medRxiv. Preprint. 2022 Nov 29. PMCID: PMC9727767

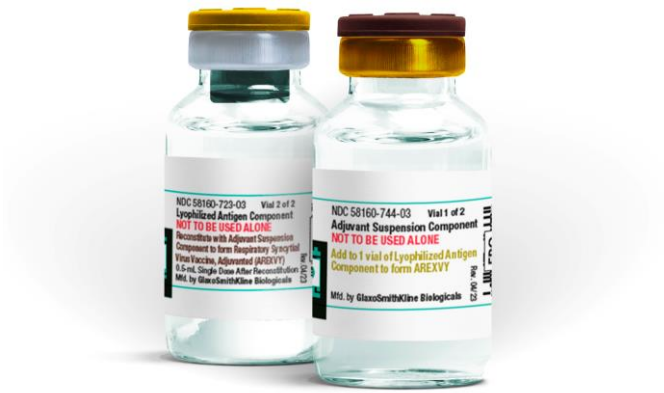
Respiratory syncytial virus

Immunization products

RSVPreF3 (Arexvy, GSK)

Adjuvanted recombinant prefusion F protein vaccine

Requires reconstitution



RSVPreF (Abrysvo, Pfizer)

Recombinant bivalent prefusion F protein vaccine

Requires reconstitution (kit)

Respiratory syncytial virus

Immunization products

Nirsevimab (Beyfortus, Sanofi/AZ)
Long-acting monoclonal antibody

Prefilled syringes

Palivizumab (Synagis, Sobi)
Monoclonal antibody

Single dose vial, no reconstitution

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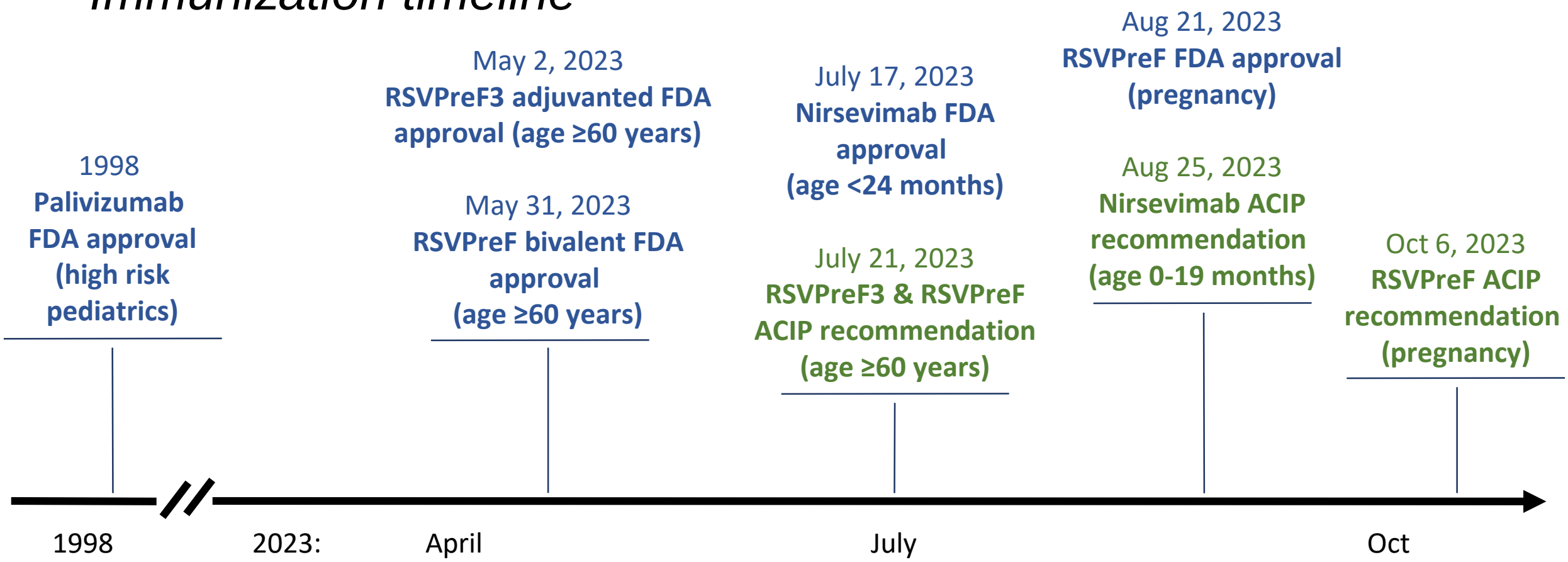
Respiratory syncytial virus

Immunization timeline



Respiratory syncytial virus

Immunization in older adults

Comparison of Phase 3 clinical trials of RSV vaccines in older adults

	RSVPreF3 adjuvanted (GSK)	RSVPreF bivalent (Pfizer)
Study design	International double-blind 1:1 randomized placebo-controlled trial (ongoing)	Multicenter double-blind 1:1 randomized placebo-controlled trial (ongoing)
Study population	Adults ≥60 years old in 17 countries representing both global hemispheres	Adults ≥60 years old in 7 countries representing both global hemispheres
Participants (n)	12,467 vaccine group + 12,499 placebo group	17,215 vaccine group + 17,069 placebo group
Primary objective(s)	RSV-related lower respiratory tract disease	RSV-associated lower respiratory tract illness with ≥2 symptoms and with ≥3 symptoms
Vaccine efficacy	**82.6% (season 1 following vaccination)** **56.1% (season 2 – interim analysis)**	**88.9% (season 1 following vaccination)** **78.6% (season 2 – interim analysis)**
Safety	**No significant difference in serious adverse events compared to placebo group except severe reactogenicity events**	**No significant difference in serious adverse events compared to placebo group except severe reactogenicity events**

MMWR Morb Mortal Wkly Rep 2023;72:793–801. N Engl J Med 2023; 388:595-608. N Engl J Med 2023; 388:1465-1477

Respiratory syncytial virus

Immunization in older adults

- **ACIP conclusion:** both RSV vaccines demonstrated moderate-to-high efficacy in preventing RSV-associated LRTD in adults ≥60 years old
- **Recommendation:** Individuals age ≥60 years may receive a single dose of either RSV vaccine, using shared clinical decision making
  - Vaccination prior to the onset of RSV season is optimal when possible
  - Co-administration with other vaccines is acceptable, though evidence is limited
- Open questions:
  - Population-level impacts of vaccination
  - Duration of protection and value of revaccination
  - Cost-effectiveness
  - Risk of inflammatory neurologic events

MMWR Morb Mortal Wkly Rep 2023;72:793–801.

Respiratory syncytial virus

Immunization in pregnancy

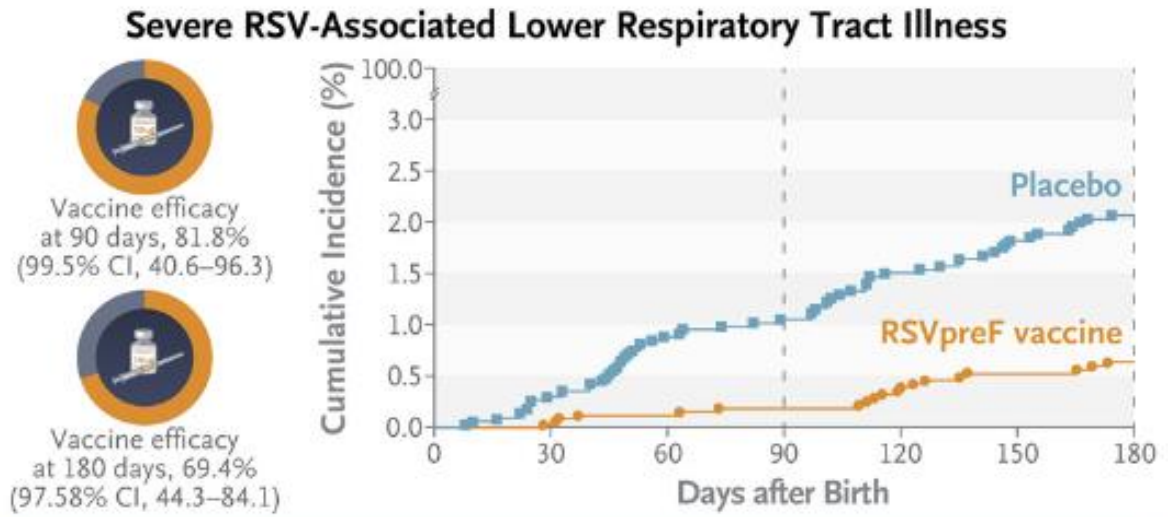
RSVPreF bivalent vaccination during pregnancy to prevent RSV illness in infants	
Study design	Phase 3,double-blind 1:1 randomized placebo-controlled trial (ongoing)
Study population	Infants born to healthy women age ≤49yo vaccinated at 24-36 weeks' gestation in uncomplicated singleton pregnancies in 18 countries representing both global hemispheres
Participants (n)	3,682 vaccine group + 3,676 placebo group
Primary objective(s)	1) Medically attended severe RSV-associated LRTI and 2) Medically attended RSV-associated LRTI within 90, 120, 150 and 180 days after birth
Vaccine efficacy	**Severe LRTI within 90 days: 81.8% (99.5% CI 40.6-96.3), within 180 days: 69.4% (97.58% CI 44.3-84.1) LRTI within 90 days: 57.1% (99.5% CI 14.7-79.8)***
Safety	**No safety signals detected in maternal participants or their infants/toddlers up to age 24mo**

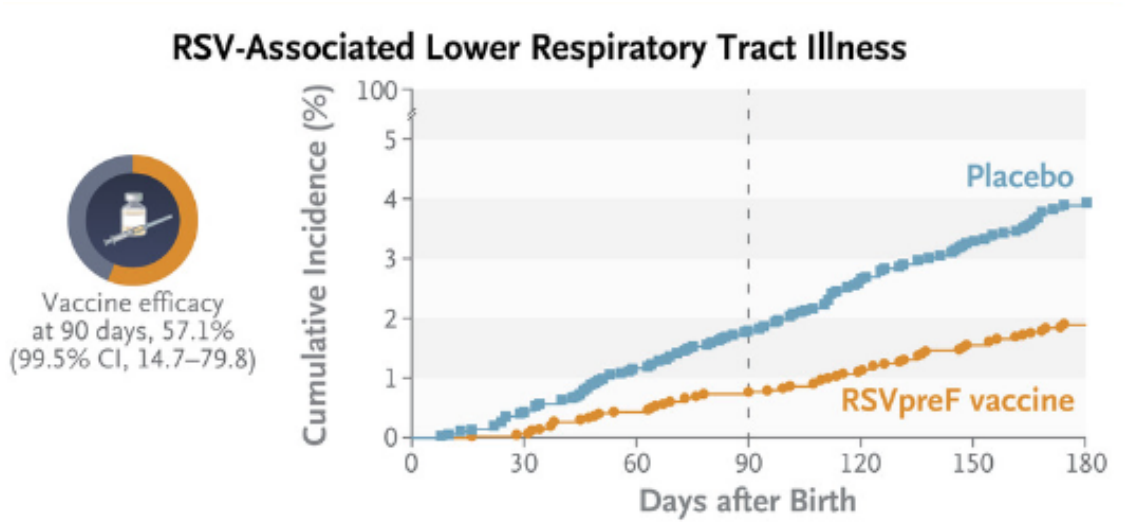
**Statistical success criteria not met*

New England Journal of Medicine. 2023;388:1451-64.

Respiratory syncytial virus

Immunization in pregnancy





Respiratory syncytial virus

Immunization in pregnant individuals

- ACIP conclusion: vaccination during pregnancy can safely and effectively reduce the risk of RSV infection
- **Recommendation:** RSV vaccine should be administered at 32-36 weeks' gestation seasonally during September-January
  - Nirsevimab should be administered after birth during RSV season if no maternal vaccination
- Co-administration with other vaccines recommended during pregnancy is a best practice
- Open question: Safety and efficacy of re-vaccination during subsequent pregnancies

MMWR Morb Mortal Wkly Rep 2023;72:1115–1122.

Respiratory syncytial virus

Passive immunization in infants

Pooled analysis of single-dose nirsevimab for prevention of RSV in infants		
Study design	Phase 2b international double-blind 2:1 randomized placebo-controlled trial	Phase 3 international double-blind 2:1 randomized placebo-controlled trial
Study population	Healthy preterm infants born at gestational age 29 weeks 0 days – 34 weeks 6 days and age 1 year or younger and entering first full RSV season in 23 countries representing both global hemispheres	Healthy term and late-preterm infants and age 1 year or younger and entering first full RSV season in 31 countries representing both global hemispheres
No. of participants	2,579 nirsevimab group + 1,293 placebo group	
Endpoints	Medically attended RSV-associated lower respiratory tract infection (LRTI) and hospitalization through 150 days after nirsevimab or placebo dose	
Efficacy	**79.0% [95% CI 68.5-86.1%] for medically attended RSV-associated LRTI 80.6% [95% CI 62.3-90.1%] for prevention of hospitalization**	
Safety	**No significant difference in serious adverse events compared to placebo group**	

MMWR Morb Mortal Wkly Rep 2023;72:920–925. N Engl J Med 2020; 383:415-425. N Engl J Med 2023; 388:1533-1534. N Engl J Med 2022; 386:837-846

Respiratory syncytial virus

Immunization in high-risk infants and children

BOX. Infants and children aged 8–19 months with increased risk for severe disease who are recommended to receive nirsevimab when entering their second respiratory syncytial virus season

Return

- Children with chronic lung disease of prematurity who required medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) any time during the 6-month period before the start of the second RSV season
- Children with severe immunocompromise
- Children with cystic fibrosis who have either 1) manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable), or 2) weight-for-length <10th percentile
- American Indian or Alaska Native children

- Efficacy estimates of nirsevimab in high-risk children is based on pharmacokinetic extrapolation from a small randomized trial
- Nirsevimab safety was comparable to palivizumab
- Nirsevimab is more cost effective than palivizumab

MMWR Morb Mortal Wkly Rep 2023;72:920–925. N Engl J Med 2022;386:892–4.

Respiratory syncytial virus

Immunization in healthy infants and children

- ACIP conclusion: nirsevimab can prevent severe RSV disease among infants and children aged <20 months
- **Recommendation 1:** All infants aged <8 months born during or entering their first RSV season should receive 1 dose of nirsevimab (weight category dosing)
  - EXCEPT those born to mothers vaccinated during pregnancy
- **Recommendation 2:** Infants and children age 8-19 months who are at increased risk for severe RSV diseases entering their second RSV season should receive 1 dose
- Providers should administer nirsevimab shortly before RSV season begins or within 1 week of birth for those born during RSV season
- Co-administration with other vaccines is a best practice
- Open question: clinical efficacy in high-risk infants and children

MMWR Morb Mortal Wkly Rep 2023;72:920–925.

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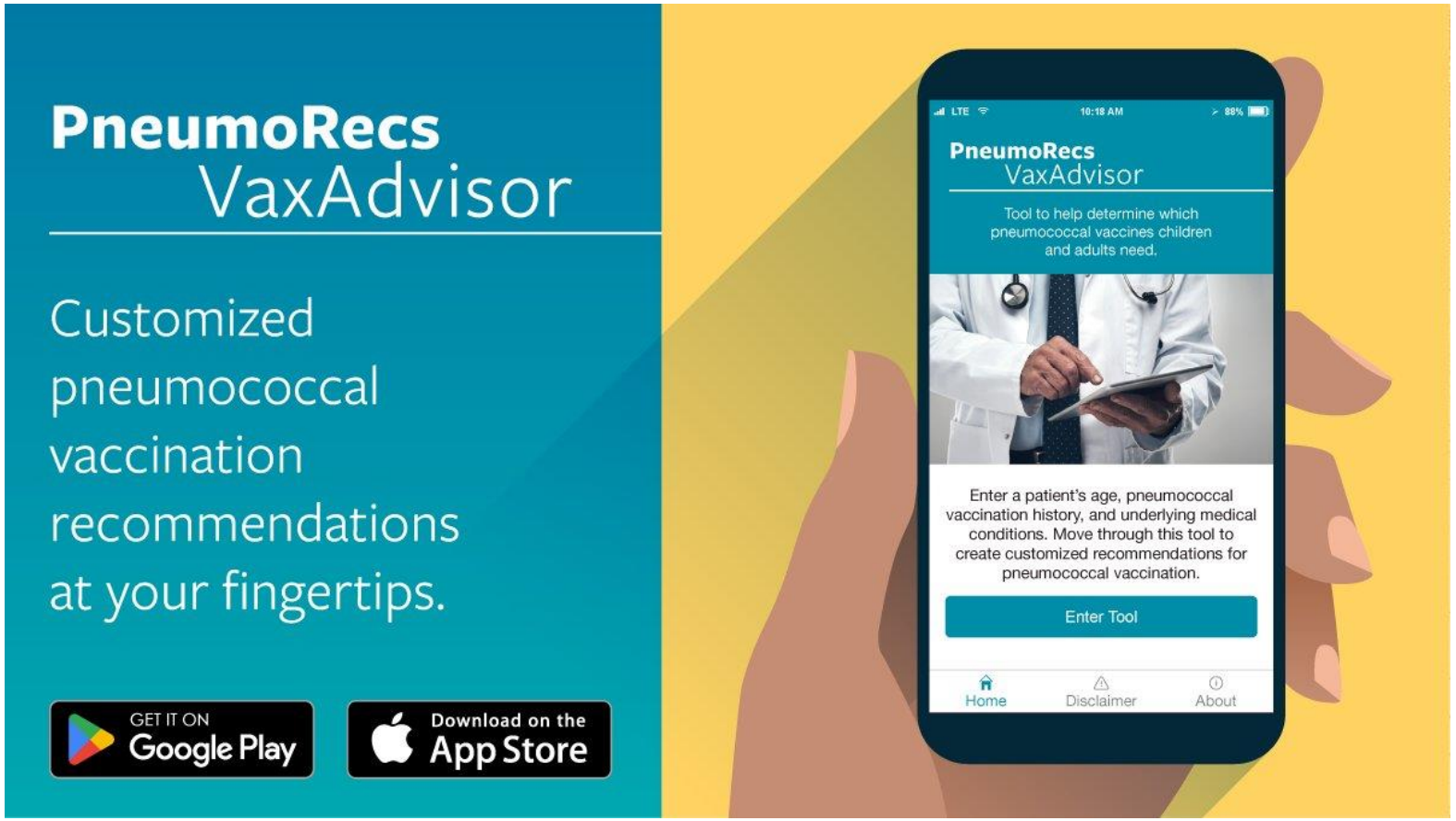
Don’t forget about pneumococcal vaccines!



CE question #1

HW is a 41-year-old female patient with a severe allergy (anaphylaxis) to eggs, and no other medical history. She has always been told she should not receive influenza vaccine. Which of the following is correct based on current CDC ACIP recommendations?

a) She should not receive any currently available influenza vaccine
b) She should only receive a non-egg-based formulation
c) She should only receive influenza vaccination in a setting where a provider is experienced in managing severe allergic reactions
d) She should receive any formulation that is appropriate for her age in any setting

CE question #1

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d) She should receive any formulation that is appropriate for her age in any setting

CE question #2

Updated 2023-2024 COVID-19 vaccines became available in the U.S. in September. Recent vaccine uptake data indicate that: **[Select all that apply]**

a) White, non-Hispanic individuals have received vaccination at rates up to 3x that of minoritized groups
b) Adults of all racial/ethnic groups are receiving vaccination at about the same rate
c) A significant majority of adults have received a dose
d) Less than 20% of adults have received a dose

CE question #2

Updated 2023-2024 COVID-19 vaccines became available in the U.S. in September. Recent vaccine uptake data indicate that: **[Select all that apply]**

a) **White, non-Hispanic individuals have received vaccination at rates up to 3x that of minoritized groups**
b) Adults of all racial/ethnic groups are receiving vaccination at about the same rate
c) **Less than 20% of adults have received a dose**
d) A significant majority of adults have received a dose

CE question #3

Studies have demonstrated that RSV immunizations can reduce the risk of severe RSV-related illness in:

a) Adults age ≥60yo
b) Infants
c) Pregnant women
d) A and B only

CE question #3

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a) Adults age ≥60yo
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CE question #4

Which of the following best describes the patterns of disparities in RSV infection among young children in the U.S.?

a) Historical disparities have mostly impacted children of all minoritized groups equally
b) Incidence was higher in Black and Hispanic children during the last two RSV seasons compared to white children
c) Socioeconomic status is not an important factor in RSV incidence
d) American Indian and Alaska Native children have historically been at a lower risk of severe RSV infection

CE question #4

Which of the following best describes the patterns of disparities in RSV infection among young children in the U.S.?

a) Historical disparities have mostly impacted children of all minoritized groups equally
b) Incidence was higher in Black and Hispanic children during the last two RSV seasons compared to white children
c) Socioeconomic status is not an important factor in RSV incidence
d) American Indian and Alaska Native children have historically been at a lower risk of severe RSV infection

Q&A

k.hurley@uci.edu

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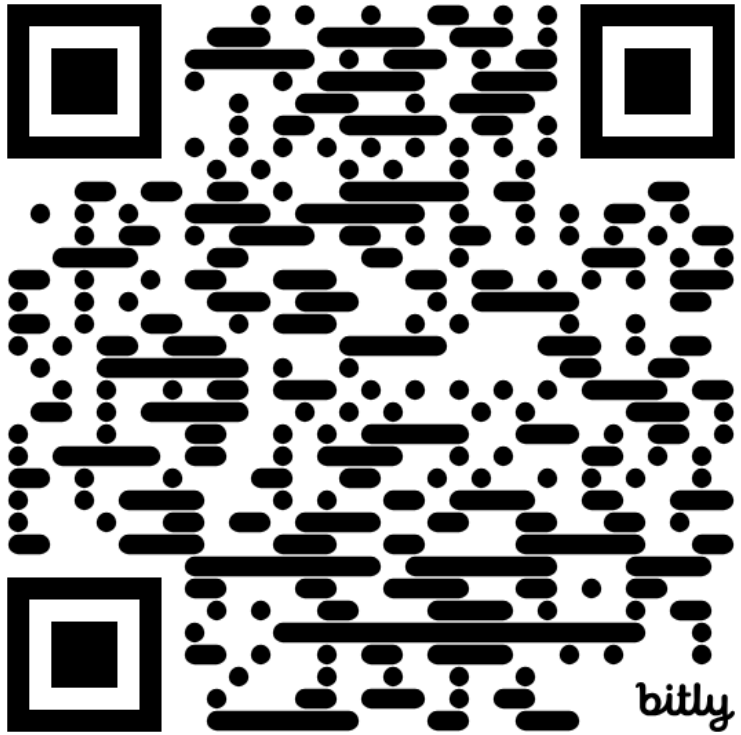

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