I-VAC Learning Collaborative for COVID-19 Vaccination

Please use your first name and health center name when you join the session

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Disclosures

- No one in a position to control the education content of the activity has any relevant financial disclosures with ineligible companies to disclose
- What gets said here today may change based on new data and recommendations
  - Knowledge is shared more rapidly through ECHO

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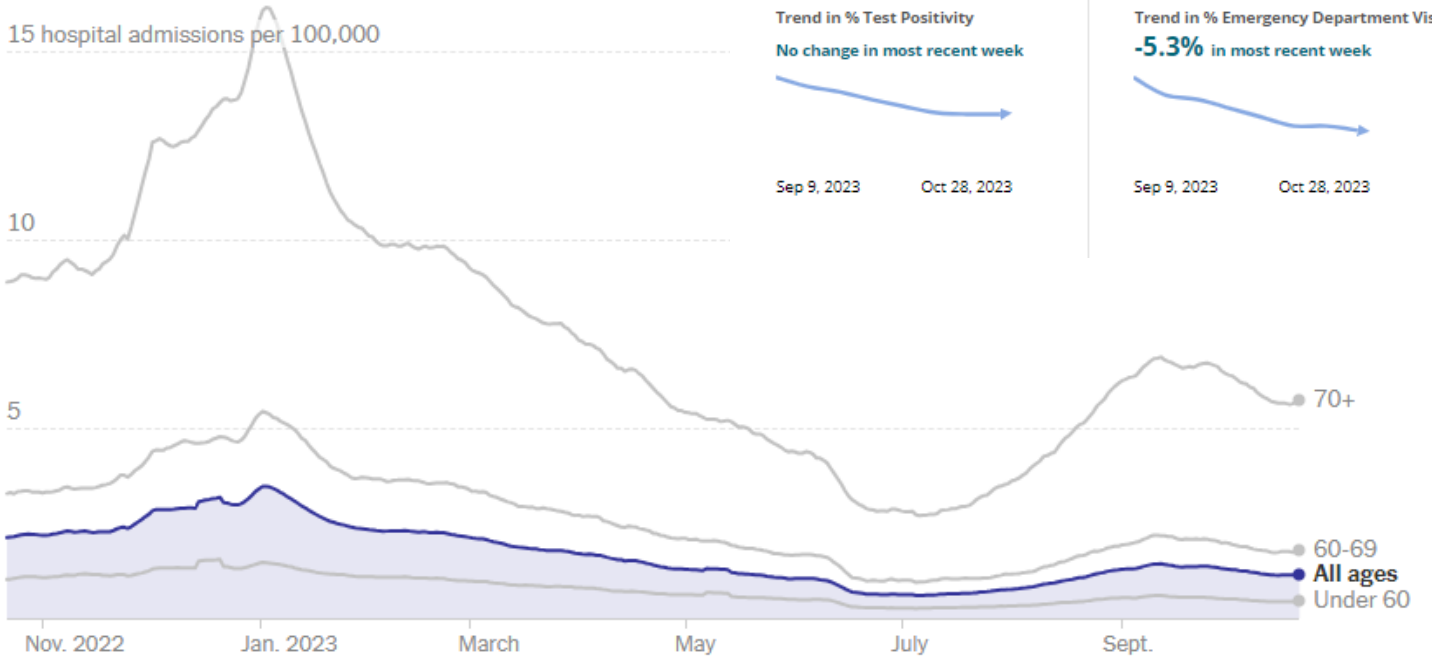
Track Covid-19 in the U.S.

Updated Nov. 7, 2023

Daily Covid hospital admissions

Avg. on Oct. 21: 3,809

14-day change: −6%



Early Indicators

Test Positivity

% Test Positivity

9.0%

(October 22 to October 28, 2023)

Trend in % Test Positivity

No change in most recent week

Sep 9, 2023 Oct 28, 2023

Emergency Department Visits

% Diagnosed as COVID-19

1.2%

(October 22 to October 28, 2023)

Trend in % Emergency Department Visits

-5.3% in most recent week

Sep 9, 2023 Oct 28, 2023

Severity Indicators

Hospitalizations

Hospital Admissions

15,745

(October 22 to October 28, 2023)

Trend in Hospital Admissions

+0.1% in most recent week

Sep 9, 2023 Oct 28, 2023

Deaths

% of All Deaths in U.S. Due to COVID-19

2.5%

(October 22 to October 28, 2023)

Trend in % COVID-19 Deaths

No change in most recent week

Sep 9, 2023 Oct 28, 2023

cdc.gov

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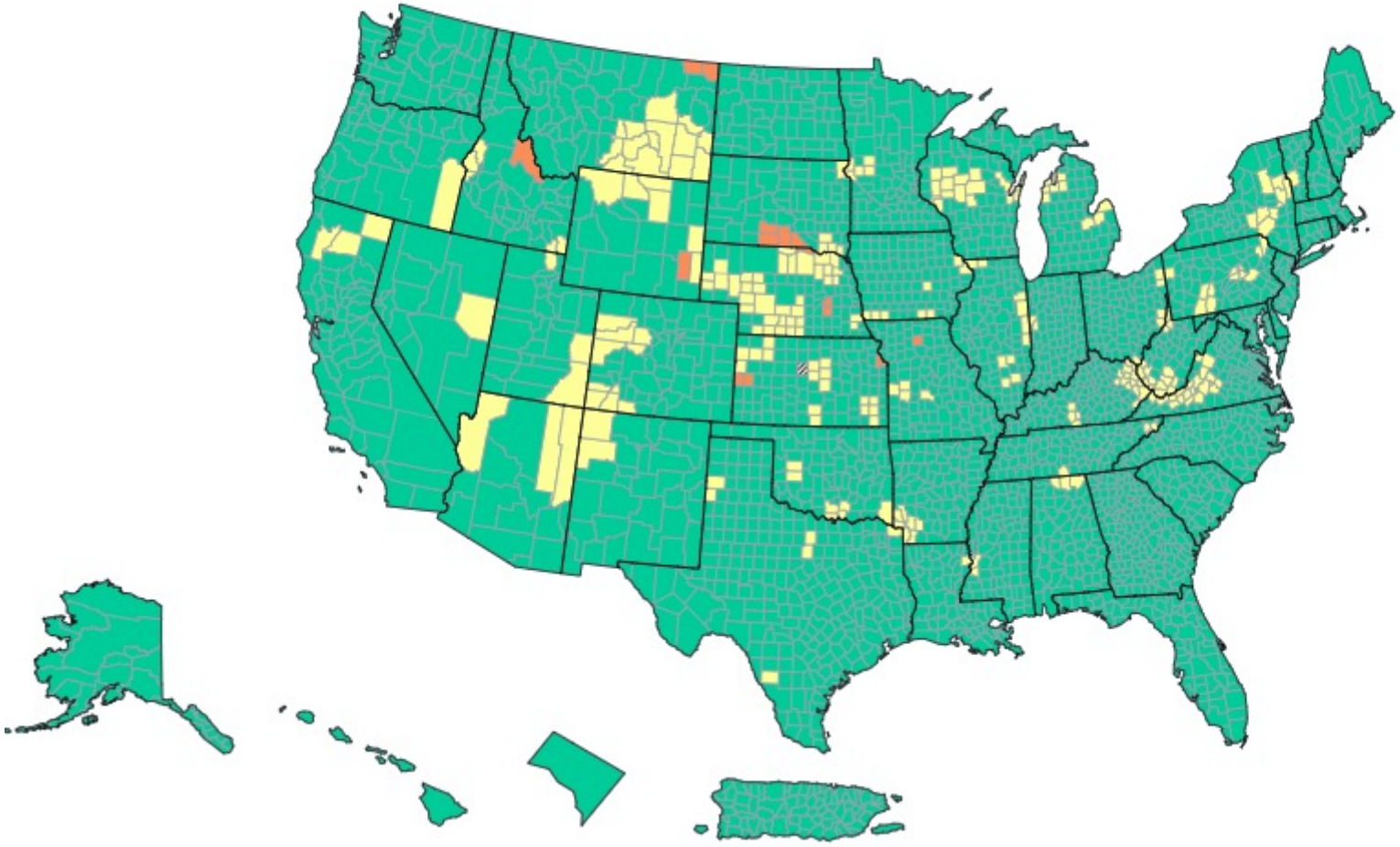
Reported COVID-19 New Hospital Admissions Rate per 100,000 Population in the Past Week, by County – United States



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cdc.gov

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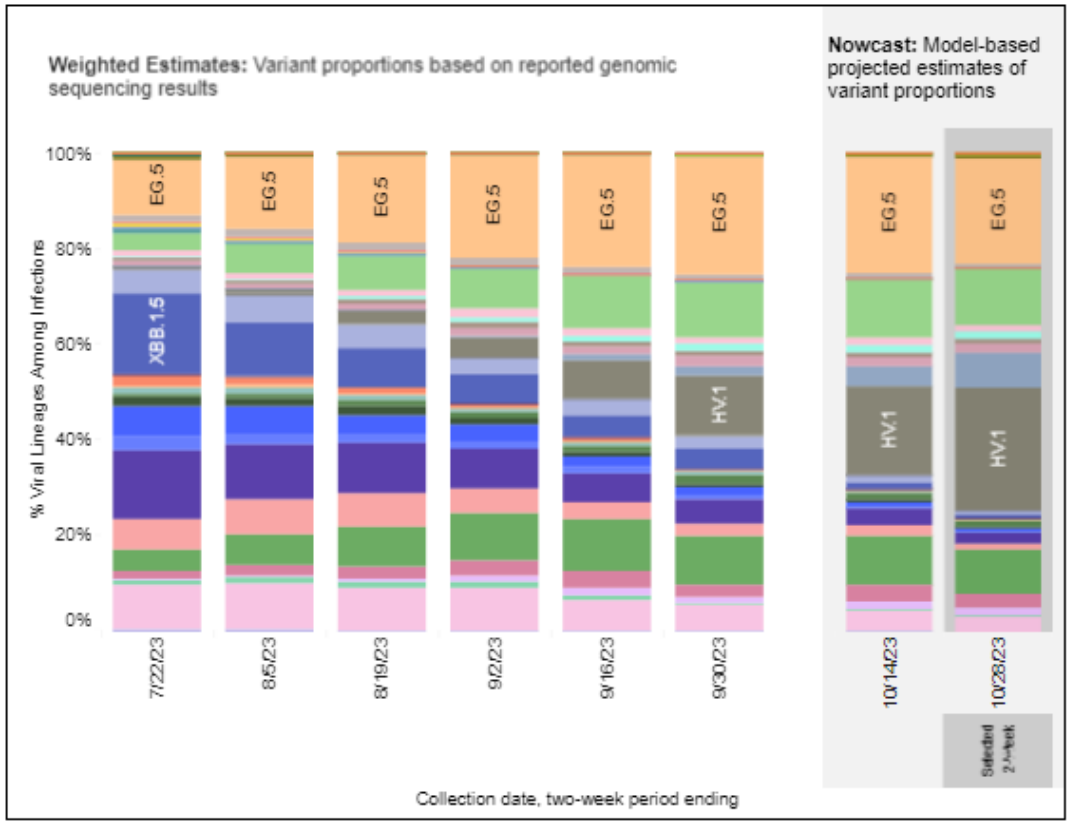
Weighted and Nowcast Estimates in United States for 2-Week Periods in 7/9/2023 – 10/28/2023

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

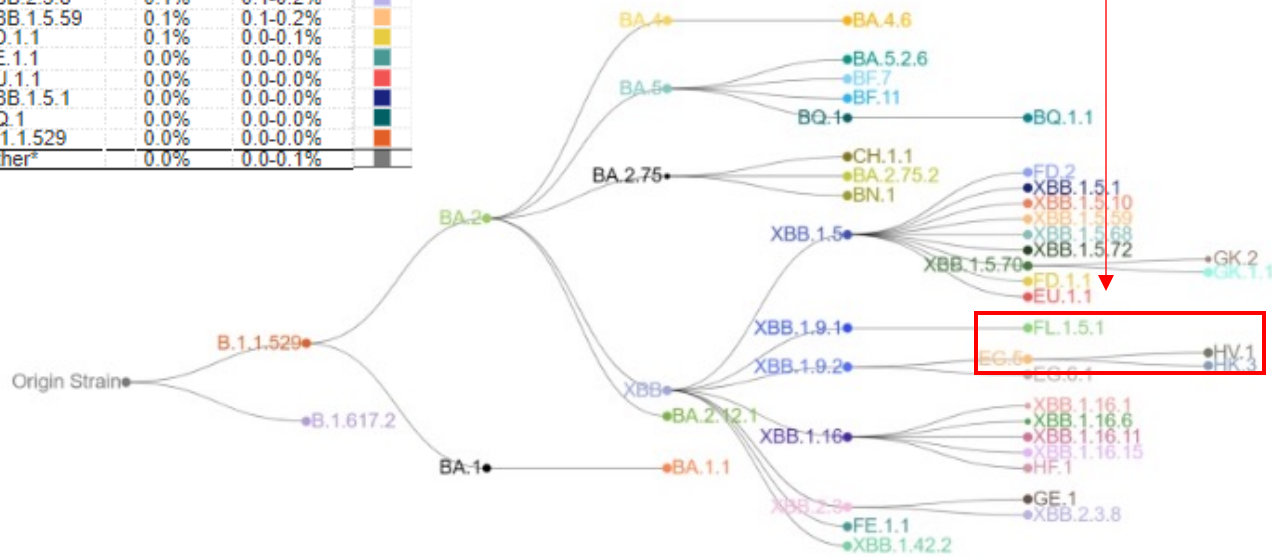


Nowcast Estimates in United States for 10/15/2023 – 10/28/2023

USA

WHO label	Lineage #	%Total	95%PI
Omicron	HV.1	25.2%	22.7-27.9%
	EG.5	21.9%	19.6-24.3%
	FL.1.5.1	12.0%	9.8-14.6%
	XBB.1.16.6	9.2%	8.0-10.5%
	HK.3	7.5%	5.6-9.9%
	XBB.1.16.11	3.1%	2.4-4.0%
	XBB.2.3	3.0%	2.5-3.6%
	XBB.1.16	2.2%	1.8-2.7%
	HF.1	1.8%	1.1-3.0%
	GK.1.1	1.8%	1.3-2.6%
	XBB.1.16.15	1.5%	1.1-2.2%
	XBB.1.16.1	1.4%	1.1-1.8%
	XBB.1.5.70	1.3%	0.8-2.1%
	GE.1	1.1%	0.8-1.5%
	XBB	1.1%	0.8-1.4%
	GK.2	0.9%	0.6-1.2%
	CH.1.1	0.8%	0.5-1.3%
	EG.6.1	0.7%	0.5-1.0%
	XBB.1.5	0.6%	0.5-0.8%
	XBB.1.9.1	0.5%	0.4-0.7%
	BA.2	0.5%	0.2-0.9%
	XBB.1.42.2	0.3%	0.2-0.6%
	XBB.1.5.72	0.3%	0.2-0.4%
	XBB.1.5.68	0.3%	0.2-0.5%
	XBB.1.9.2	0.3%	0.2-0.4%
	XBB.1.5.10	0.2%	0.1-0.2%
	XBB.2.3.8	0.1%	0.1-0.2%
	XBB.1.5.59	0.1%	0.1-0.2%
	FD.1.1	0.1%	0.0-0.1%
	FE.1.1	0.0%	0.0-0.0%
	EU.1.1	0.0%	0.0-0.0%
	XBB.1.5.1	0.0%	0.0-0.0%
	BQ.1	0.0%	0.0-0.0%
	B.1.1.529	0.0%	0.0-0.0%
Other	Other*	0.0%	0.0-0.1%

~60%



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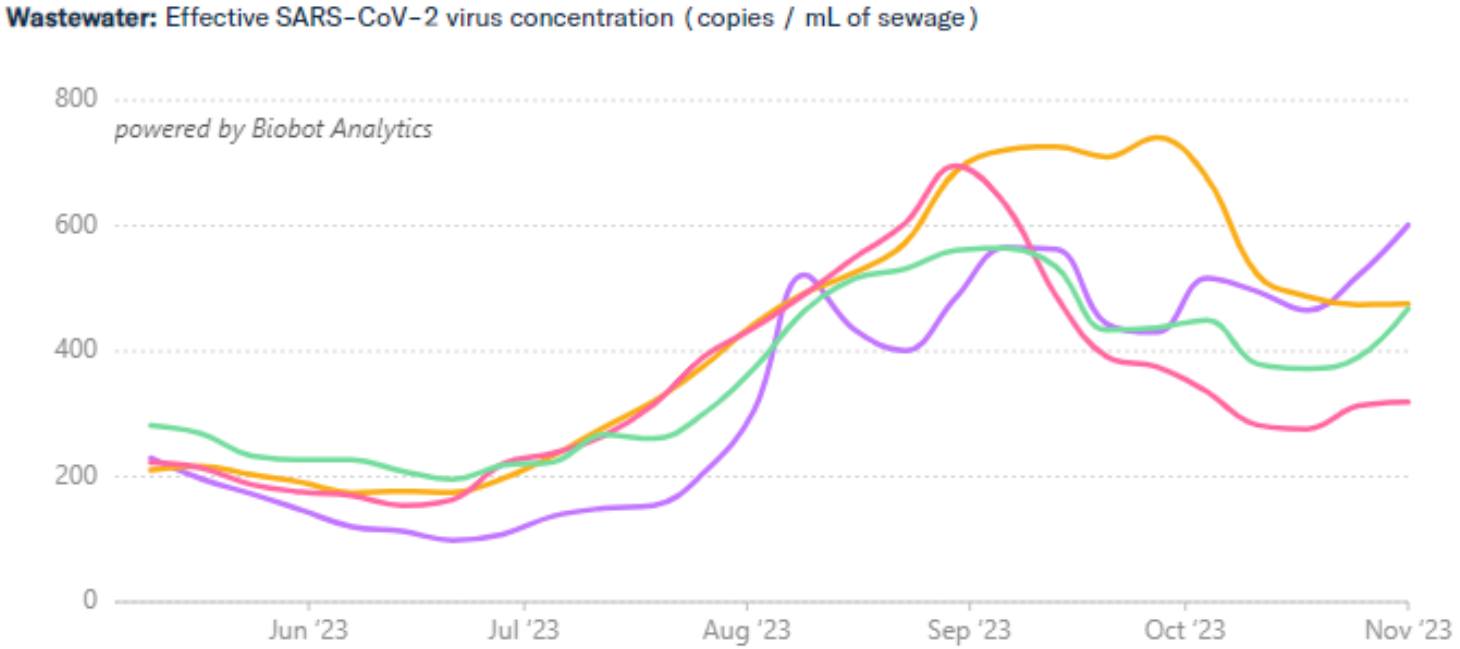
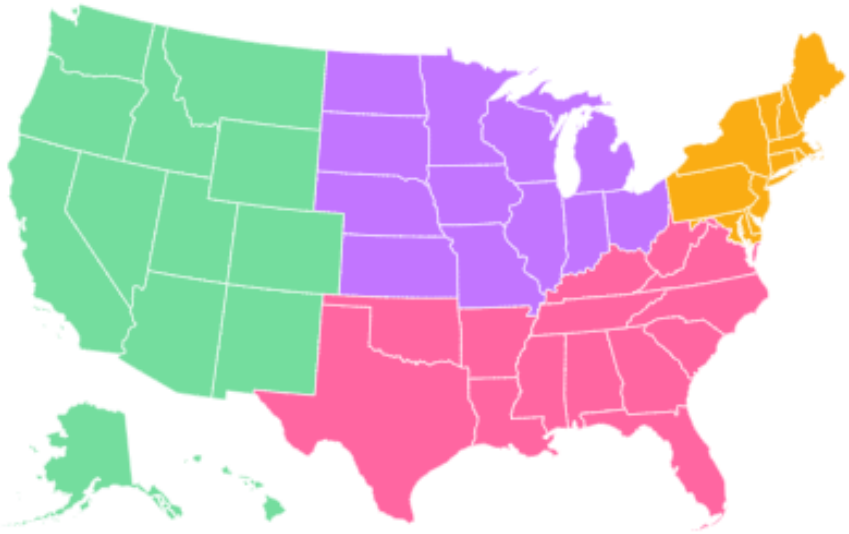
Wastewater Analysis





Source: Wastewater data from Biobot Analytics

https://biobot.io/data/

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More Than 15M Americans Have Received Updated COVID-19 Vaccines So Far, HHS Says

- Over 15 million people in the United States, around 4.5% of the population, had received the updated COVID-19 shots by Oct. 27, a Department of Health and Human Services (HHS) spokesperson said on Wednesday, lagging behind last year's vaccinations.
- 23 million people had received updated boosters as of Oct. 26 last year
- 56.5 million people 17% of the U.S. population, received last year's version of the vaccines.

Newborn and Early Infant Outcomes Following Maternal COVID-19 Vaccination During Pregnancy

- Population-based retrospective cohort study took place in Ontario, Canada, using multiple linked health administrative databases. Singleton live births with an expected delivery date between May 1, 2021, and September 2, 2022, were included
- 142 006 infants were included; 85 670 were exposed to 1 or more COVID-19 vaccine doses in utero (60%).
- Infants of vaccinated mothers with mRNA COVID-19 vaccination during pregnancy was associated with lower risks of SNM, neonatal death, and NICU admission. In addition, neonatal and 6-month readmissions were not increased in infants of mothers vaccinated during pregnancy.

Table 3. Association Between COVID-19 Vaccination During Pregnancy and Neonatal and Infant Outcomes

	No./total No. (%)		Risk ratio or hazard ratio (95% CI)	
Outcome	Vaccine exposed	Unexposed	Crude	Adjusted[a]
Severe neonatal morbidity	6229/85 670 (7.3)	4697/56 336 (8.3)	0.87 (0.84-0.90)	0.86 (0.83-0.90)
Neonatal death	74/85 670 (0.09)	91/56 336 (0.16)	0.53 (0.39-0.73)	0.47 (0.33-0.65)
Neonatal intensive care unit admission	9721/85 670 (11.4)	7391/56 336 (13.1)	0.86 (0.84-0.89)	0.86 (0.83-0.89)
Neonatal readmission	4664/84 798 (5.5)	2820/55 417 (5.1)	1.08 (1.03-1.13)	1.03 (0.98-1.09)
Discharged within 7 d after birth	4588/82 581 (5.6)	2769/53 330 (5.2)	1.07 (1.02-1.12)	1.03 (0.97-1.08)
Hospital admission up to 6 mo of age	5361/63 834 (8.4)	3941/48 625 (8.1)	1.04 (1.00-1.08)	1.01 (0.96-1.05)
Discharged within 7 d after birth	5020/61 426 (8.2)	3611/46 007 (7.9)	1.04 (1.00-1.09)	1.01 (0.97-1.06)

JAMA Pediatr. Published online October 23, 2023. doi:10.1001/jamapediatrics.2023.4499

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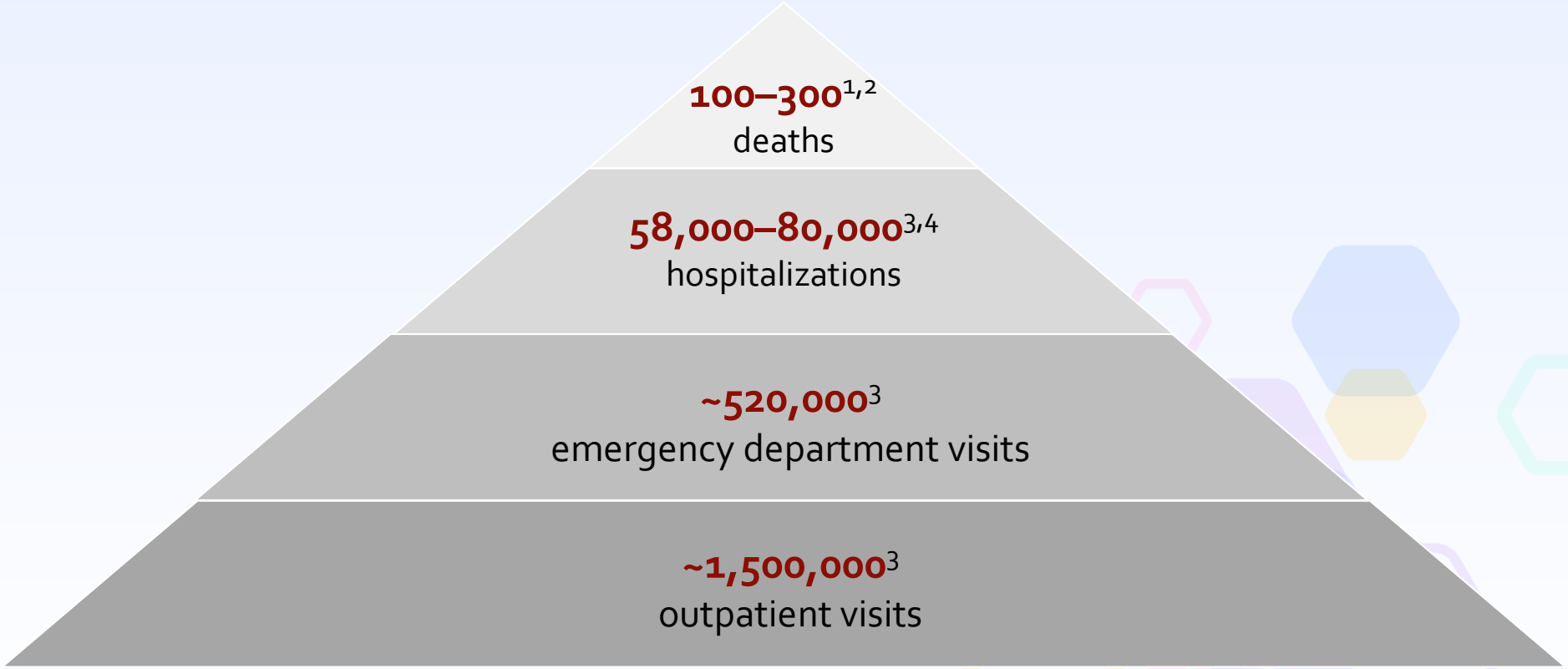
RSV Vaccination in Pregnancy

Rational for Neonatal Protection

Edward Linn, MD

Each year in U.S. children aged less than 5 years, RSV is associated with…



[1]Thompson et al, JAMA, 2003; [2]Hansen et al, JAMA Network Open, 2022; [3]Hall et al, NEJM, 2009; [4]McLaughlin et al, J Infect Dis, 2022 (*estimate 80,000 hospitalizations in infants <1y)

RSV is the leading cause of hospitalization in U.S. infants[1]

- Most (68%) infants are infected in the first year of life and nearly all (97%) by age 2 years[2]
- 2-3% of young infants will be hospitalized for RSV[3,4,5]
- RSV is a common cause of lower respiratory tract infection in infants
- Highest RSV hospitalization rates occur in first months of life and risk declines with increasing age in early childhood[3,5]
- 79% of children hospitalized with RSV aged <2 years had no underlying medical conditions[3]

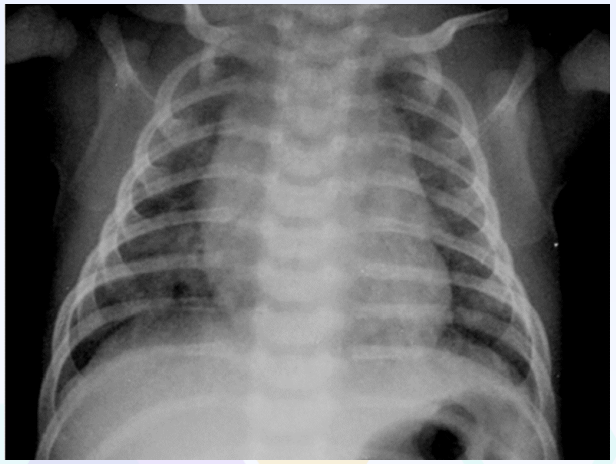
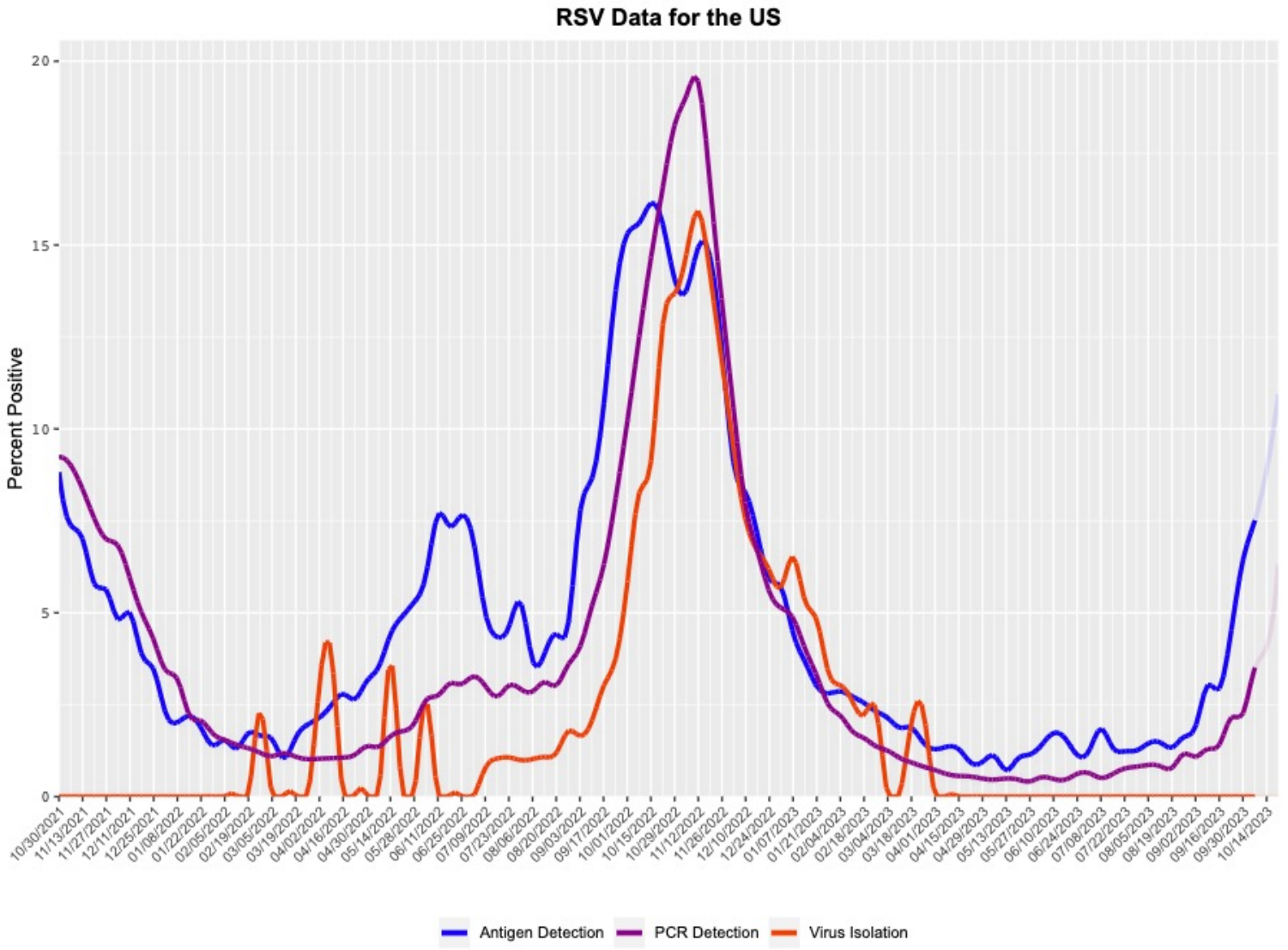


Image: Goncalves et al. Critical Care Research and Practice 2012

[1]Suh et al. JID 2022; [2]Glezen et al, Arch Dis Child, 1986; [3]Hall et al, Pediatrics, 2013; [4]Langley & Anderson, PIDJ, 2011; [5]CDC NVSN data

Where are we with RSV Infections



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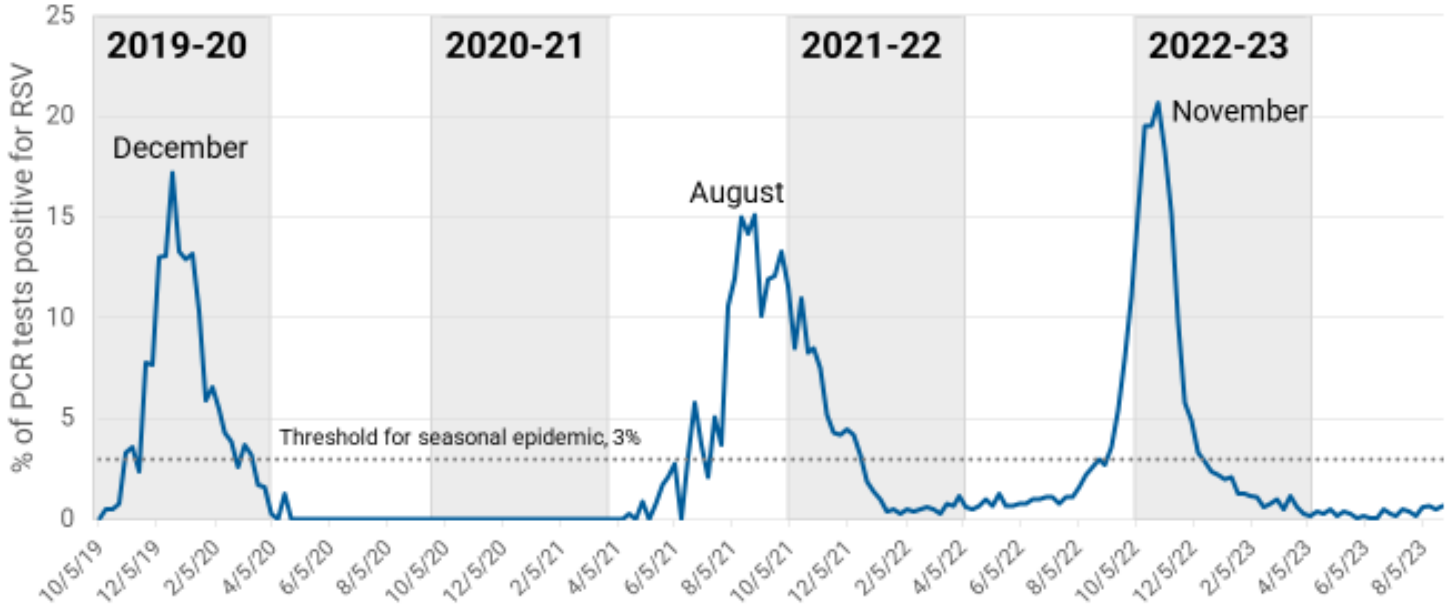
RSV in Chicago

While RSV seasonality in Chicago has been disrupted since the COVID-19 pandemic, RSV activity has been low this summer.

Local epidemiology supports October start to nirsevimab administration.



Gray boxes represent typical RSV season, October-March. Source: Aggregate, weekly PCR test results from a convivence sample of Chicago hospital laboratories and a commercial laboratory serving Chicago healthcare facilities. Data reported through 8/26/2023.

What's New? As of 8/22/23…

FDA U.S. FOOD & DRUG ADMINISTRATION

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FDA NEWS RELEASE

FDA Approves First Vaccine for Pregnant Individuals to Prevent RSV in Infants

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More Press Announcements

For Immediate Release: August 21, 2023

Español

Today, the U.S. Food and Drug Administration approved Abrysvo (Respiratory Syncytial Virus Vaccine), the first vaccine approved for use in pregnant individuals to prevent lower respiratory tract disease (LRTD) and severe LRTD caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age. Abrysvo is approved for use at 32 through 36 weeks gestational age of pregnancy. Abrysvo is administered as a single dose injection into the muscle. The FDA approved Abrysvo in May for the prevention of LRTD caused by RSV in individuals 60 years of age and older.

"RSV is a common cause of illness in children, and infants are among those at highest risk for severe disease, which can lead to hospitalization," said Peter Marks, M.D., Ph.D., director of the FDA's Center for Biologics Evaluation and Research. "This approval provides an option for healthcare providers and

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08/22/2023

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https://www.fda.gov/news-events/press-announcements/fda-approves-first-vaccine-pregnant-individuals-prevent-rsv-infants

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What drove the FDA decision to approve abrysvo for pregnancy?

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AREXVY is not approved for use in pregnancy

GSK halts its trials

In February 2022, GSK halted enrolment and vaccination across three phase 3 trials of its maternal RSV vaccine candidate, citing a safety signal in one of them.

It emerged that the concern was about an increased risk of preterm birth in the vaccine arm.

In a document submitted to the FDA, GSK's data showed 238 preterm births out of 3496 (6.8%) in the vaccine arm and 86 out of 1739 (4.9%) in the placebo arm—around one extra preterm birth for every 54 vaccinated mothers.
There were 13 neonatal deaths in the vaccine arm and three in the placebo arm.

https://www.bmj.com/content/381/bmj.p1021

FDA approval for RSVpreF vaccine

- On August 21, 2023, FDA approved Pfizer RSVpreF vaccine for use in pregnant people for the prevention of RSV lower respiratory tract disease and severe lower respiratory tract disease in infants from birth to 6 months of age
- Approved as a single dose to be given at 32–36 weeks gestation
  - In phase 2b and 3 trials, vaccination was given during 24–36 weeks gestation
  - A numerical imbalance in preterm births was observed in RSVpreF vaccine compared to placebo recipients in two clinical studies
  - Available data are insufficient to establish or exclude a causal relationship between preterm birth and RSVpreF
  - Additionally, a numerical imbalance in hypertensive disorders of pregnancy was observed in RSVpreF vaccine compared to placebo recipients

FDA Approves First Vaccine for Pregnant Individuals to Prevent RSV in Infants | FDA
Package Insert - ABRYSVO (STN 125768) (fda.gov)
August 21, 2023 Approval Letter - ABRYSVO (STN 125768) (fda.gov)

- MATISSE Trial:
  - RCT examined efficacy and safety of RSVpreF vaccine between 24-26 weeks
  - International
  - Phase 3
  - Double-blind, placebo-controlled
  - Met criteria for vaccine efficacy at the prespecified interim analysis

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 APRIL 20, 2023 VOL. 388 NO. 16

Bivalent Prefusion F Vaccine in Pregnancy to Prevent RSV Illness in Infants

B. Kampmann, S.A. Madhi, I. Munjal, E.A.F. Simões, B.A. Pahud, C. Llapur, J. Baker, G. Pérez Marc, D. Radley, E. Shittu, J. Glanternik, H. Snaggs, J. Baber, P. Zachariah, S.L. Barnabas, M. Fausett, T. Adam, N. Perreras, M.A. Van Houten, A. Kantele, L.-M. Huang, L.J. Bont, T. Otsuki, S.L. Vargas, J. Gullam, B. Tapiero, R.T. Stein, F.P. Polack, H.J. Zar, N.B. Staerke, M. Duron Padilla, P.C. Richmond, K. Koury, K. Schneider, E.V. Kalinina, D. Cooper, K.U. Jansen, A.S. Anderson, K.A. Swanson, W.C. Gruber, and A. Gurtman, for the MATISSE Study Group*

ABSTRACT

BACKGROUND

Whether vaccination during pregnancy could reduce the burden of respiratory syncytial virus (RSV)–associated lower respiratory tract illness in newborns and infants is uncertain.

METHODS

In this phase 3, double-blind trial conducted in 18 countries, we randomly assigned, in a 1:1 ratio, pregnant women at 24 through 36 weeks' gestation to receive a single intramuscular injection of 120 μg of a bivalent RSV prefusion F protein–based (RSVpreF) vaccine or placebo. The two primary efficacy end points were medically attended severe RSV-associated lower respiratory tract illness and medically attended RSV-associated lower respiratory tract illness in infants within 90, 120, 150, and 180 days after birth. A lower boundary of the confidence interval for vaccine efficacy (99.5% confidence interval [CI] at 90 days; 97.58% CI at later intervals) greater than 20% was considered to meet the success criterion for vaccine efficacy with respect to the primary end points.

RESULTS

At this prespecified interim analysis, the success criterion for vaccine efficacy was met with respect to one primary end point. Overall, 3682 maternal participants received vaccine and 3676 received placebo; 3570 and 3558 infants, respectively, were evaluated. Medically attended severe lower respiratory tract illness occurred within 90 days after birth in 6 infants of women in the vaccine group and 33 infants of women in the placebo group (vaccine efficacy, 81.8%; 99.5% CI, 40.6 to 96.3); 19 cases and 62 cases, respectively, occurred within 180 days after birth (vaccine efficacy, 69.4%; 97.58% CI, 44.3 to 84.1). Medically attended RSV-associated lower respiratory tract

The authors' full names, academic degrees, and affiliations are listed in the Appendix. Dr. Munjal can be contacted at iona.munjal@pfizer.com or at Vaccine Research and Development, Pfizer, 401 N. Middletown Rd., Pearl River, NY 10965.

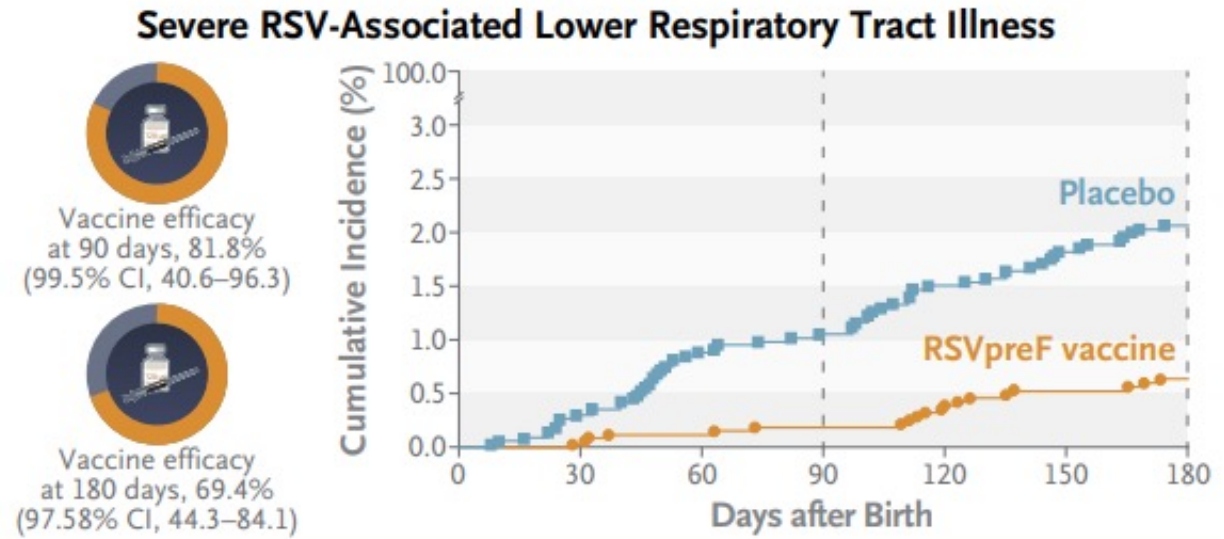
*The members of the MATISSE Study Group are listed in the Supplementary Appendix, available at NEJM.org.

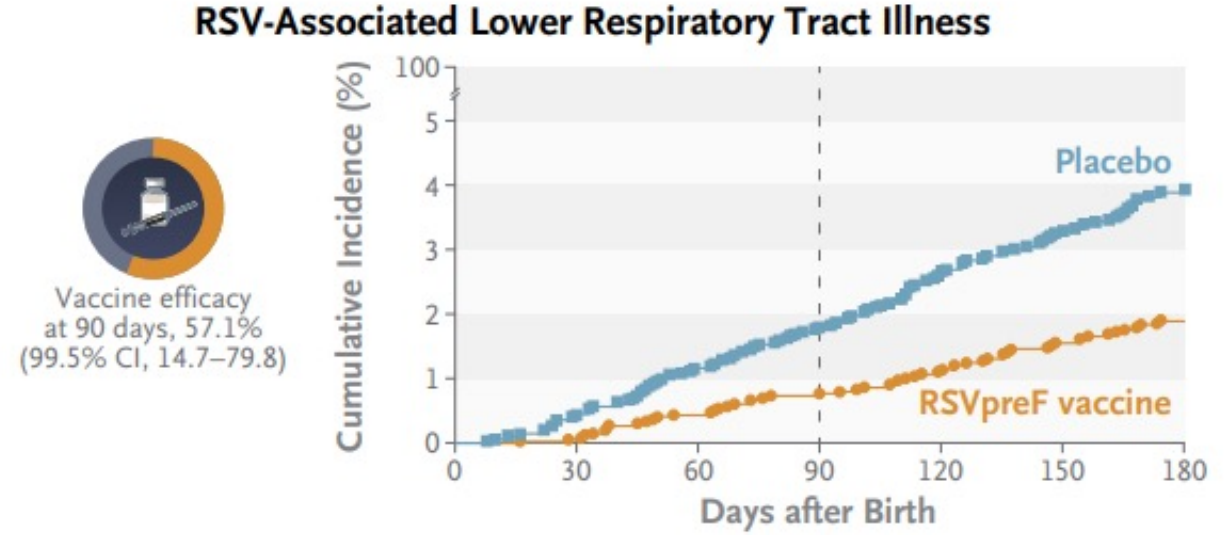
Drs. Kampmann, Madhi, and Munjal contributed equally to this article.

This article was published on April 5, 2023, at NEJM.org.

N Engl J Med 2023;388:1451-64.
DOI: 10.1056/NEJMoa2216480

Vaccine efficacy





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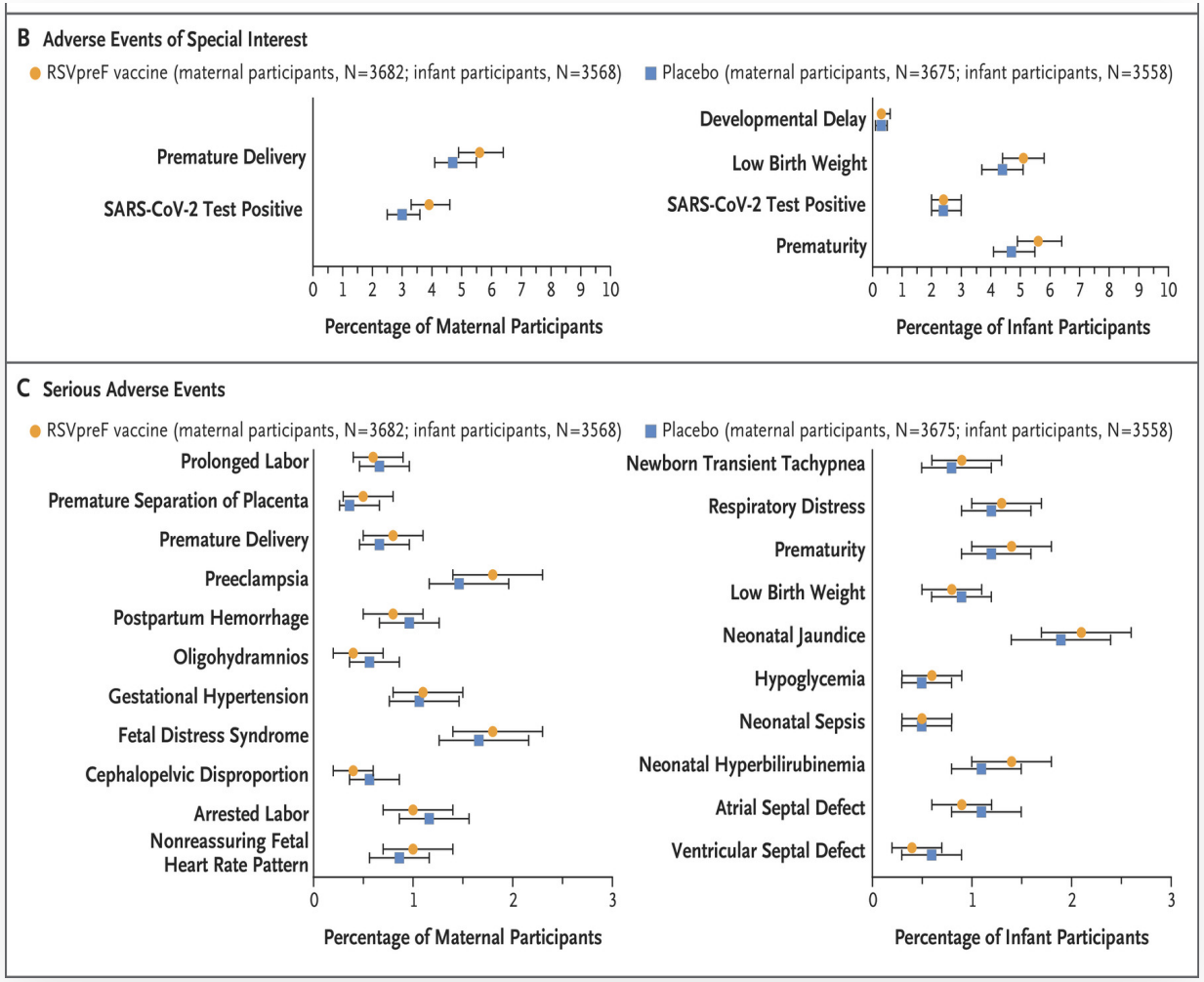
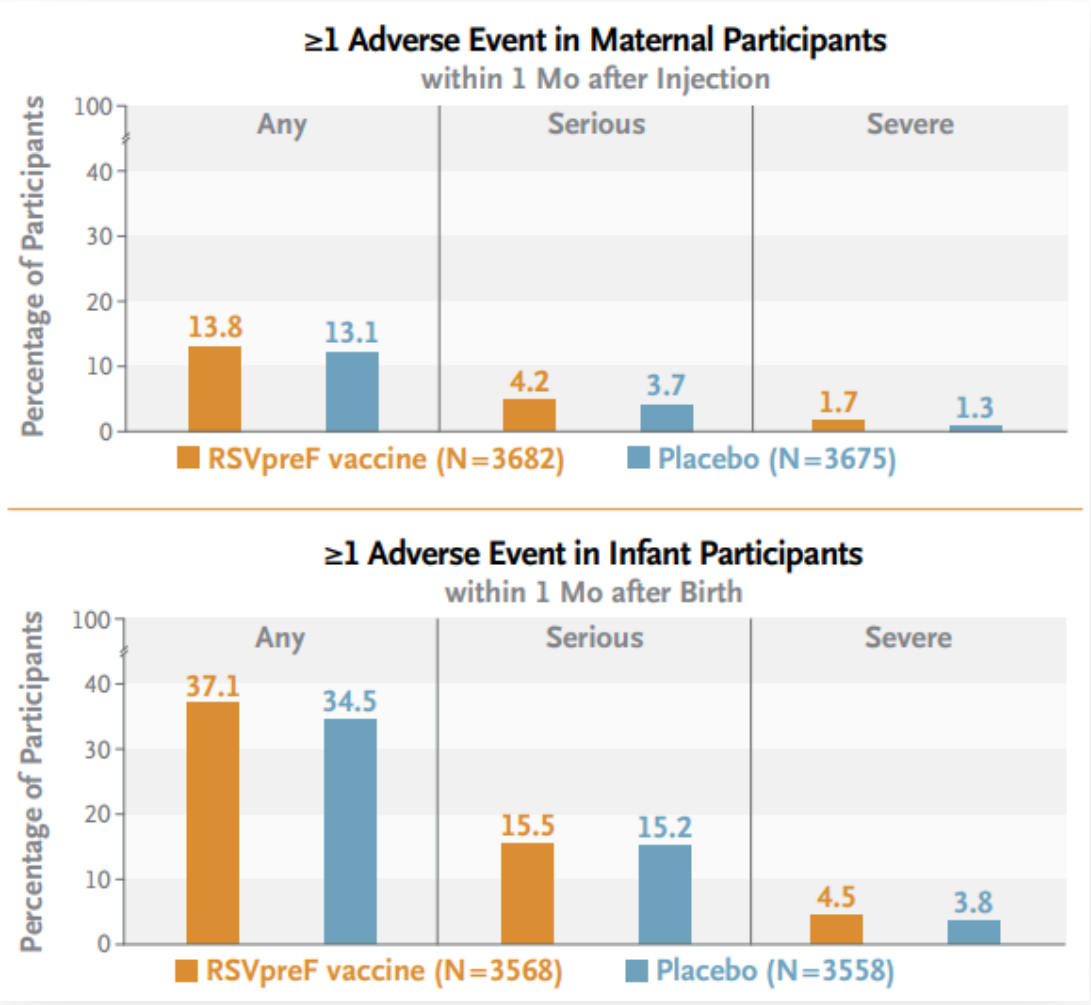
Vaccine safety and side effects





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Conclusions

- When administered to pregnant people in pregnancy, the RSVpreF vaccine was effective against medically attended severe RSV-associated respiratory tract illness in infants
- No safety signals detected in mothers or infants
- Limitations:
  - High-risk pregnancies excluded
  - Study may be too small to know if the PTB difference is significantG
  - Limited data from low-income countries
  - Conducted during COVID-19 pandemic – disruption of typical RSV circulation

FDA Guidance

- Priority Review status and Fast Track process of approval
- Abrysvo – RSV vaccine – approved for 32-36 weeks gestational age as a single IM dose for prevention of lower respiratory tract disease in infants from birth to 6 months
- FDA is requiring postmarketing surveillance for
  - PTB – “numerical imbalance in preterm births in Abrysvo recipients (5.7%) occurred compared to those who received placebo (4.7%)
  - Preeclampsia (1.8% vs 1.4%)
- FDA guidance is for a different gestational age window than the study

HAN
HEALTH ALERT NETWORK

Distributed via the CDC Health Alert Network
October 23, 2023, 3:30 PM ET

Limited Availability of Nirsevimab in the United States—Interim CDC Recommendations to Protect Infants from Respiratory Syncytial Virus (RSV) during the 2023–2024 Respiratory Virus Season

"Expectant parents should talk with their healthcare provider about receiving the RSV vaccine (Abrysvo, Pfizer) during pregnancy to protect their infant from severe RSV. CDC recommends that all infants are protected against RSV through either vaccination of the mother with RSV vaccine during pregnancy or giving the infant nirsevimab after birth."

ACOG, SMFM, and AAP Statement on Nirsevimab Shortage

ACOG and the Society for Maternal-Fetal Medicine **continue to recommend** Pfizer's RSVpreF vaccine (Abrysvo) for pregnant patients who are from 32 weeks and zero days to 36 weeks and six days of gestation as a safe and effective option for preventing severe RSV illness in infants. Particularly in areas where nirsevimab is unavailable, maternal RSV vaccination should be encouraged.

The American Academy of Pediatrics recommends pediatricians prioritize immunizing infants with nirsevimab, when available, according to the **CDC advisory** and continue to use palivizumab while nirsevimab is limited.

Obstetric Care Professionals Recommend RSV Vaccine for Pregnant Individuals

ACOG Clinical | Oct 13, 2023

- RSV is a potentially serious and even deadly disease for young children and infants. That is why, collectively, the *American Academy of Family Physicians; American College of Nurse-Midwives; American College of Obstetricians and Gynecologists; Association of Women's Health, Obstetric and Neonatal Nurses; National Association of Nurse Practitioners in Women's Health;* and the *Society for Maternal-Fetal Medicine* unequivocally support the CDC's new recommendations for RSV vaccination during pregnancy to prevent lower respiratory tract infections (LRTI) in infants.
- Either RSV vaccination during pregnancy at 32–36 weeks of gestation or nirsevimab immunization for infants aged less than eight months born during or entering their first RSV season is recommended. However, administration of both products is not needed for most infants.
- By recommending RSV vaccination during pregnancy or monoclonal antibody immunization for infants of pregnant people who were not vaccinated, we can reduce hospitalizations and deaths related to RSV LRTI among infants.

Maternal Respiratory Syncytial Virus Vaccination

ACOG Practice Advisory September 2023

Summary of Key Recommendations and Points

- The American College of Obstetricians and Gynecologists (ACOG) recommends a single dose of Pfizer's RSV vaccine (Abrysvo) for pregnant individuals between 32 0/7 and 36 6/7 weeks of gestation, using seasonal administration, to prevent RSV lower respiratory tract infection in infants. For most of the United States, RSV season occurs from September through January.
- Clinicians should counsel patients about the maternal RSV vaccine and the monoclonal antibody, nirsevimab, as safe and effective ways to prevent severe LRTI caused by RSV in infants.
- Patient preferences should be considered when determining whether to administer the maternal RSV vaccine or not to administer the maternal RSV vaccine and rely on administration of nirsevimab to the infant after birth.
- Maternal RSV vaccine can be administered at the same time as other vaccines routinely recommended during pregnancy.
- Clinicians should document receipt or declination of maternal RSV vaccination in the patient's medical chart.
- The only RSV vaccine approved for use during pregnancy is Pfizer's bivalent RSVpreF vaccine, Abrysvo.
- GSK's RSV vaccine, Arexvy, is **not approved** for use in pregnancy.

Areas to watch

Post-marketing surveillance is required

- Future study in high-risk (for PTB and for RSV) populations
- Study in low-income countries

ACOG and SMFM guidance

CDC Advisory Committee on Immunization Practices (ACIP) guidance

Insurance coverage and vaccine distribution

Questions?

Next Session: Tuesday, November 21st

For any questions, email us at
pgower@peds.bsd.uchicago.edu

Funding for this project was made possible by the Office of Disease Control, through the Illinois Department of Public Health.

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