

Epidemiology of America

SAFE HEALTHCARE FOR ALL





The Rapid Response Podcasts



SHEA

COVID-19 Updates: What We Know Now

Newest Episodes:

• To Mask or Not to Mask as Part of Standard Precautions?

AVAILABLE ON:









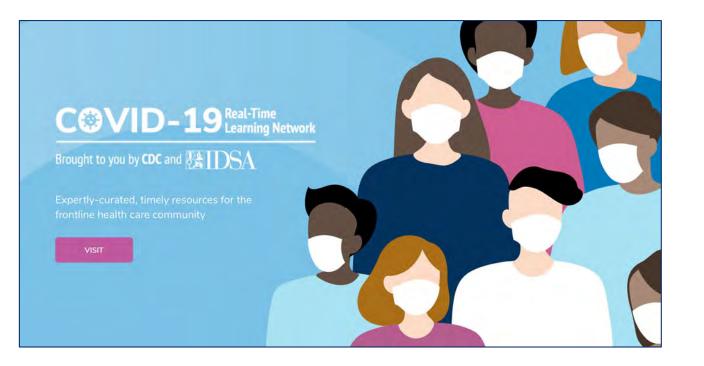
SAFE HEALTHCARE FOR ALL

TUNE IN TO THE SHEA JOURNALS PODCASTS





COVID-19 Real-Time Learning Network



SHEA

Specialty Society Collaborators:

- American Academy of Family Physicians
- American Academy of Pediatrics
- American College of Emergency Physicians
- American College of Physicians
- American Geriatrics Society
- American Thoracic Society
- Pediatric Infectious Diseases Society
- Society for Critical Care Medicine
- Society for Healthcare Epidemiology of America
- Society of Hospital Medicine
- Society of Infectious Diseases Pharmacists

With funding from the Centers for Disease Control and Prevention, IDSA has launched the COVID-19 Real Time Learning Network, an online community that brings together information and opportunities for discussion on latest research, guidelines, tools and resources from a variety of medical subspecialties around the world.

www.COVID19LearningNetwork.org @RealTimeCOVID19 | #RealTimeCOVID19

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An online learning module designed with frontline healthcare personnel in mind.

PreventionCHKC.org



ICHE Journal – Fast Tracking COVID Article Submissions

Infection Control Hospital Epidemiology Artist: Lona Mod MBRIDGI

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SAFE HEALTHCARE FOR ALL

SHEA Webinar

COVID-19 Town Hall Round 91

House Keeping Items





- Technical difficulties? Visit: <u>https://support.zoom.us</u>
- Webinar recording, PowerPoint presentation, and references available LearningCE' s <u>Rapid Response</u> <u>Program</u>
- Streaming Live on SHEA's Facebook page
- Zoom Q&A and Chat



SAFE HEALTHCARE FOR ALL

SHEA Town Hall 91 Overview

SARS-CoV-2 VARIANTS, US, CDC

Weighted and Nowcast Estimates in United States for 2-Week Nov Periods in 5/28/2023 – 9/16/2023 for 9

Nowcast Estimates in United States for 9/3/2023 – 9/16/2023

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

lineage's estimat

USA Nowcast: Model-based Weighted Estimates: Variant proportions based on reported WHO label Lineage # %Total 95%P projected estimates genomic sequencing results of variant proportion 22 5-26 6% Omicron 24.59 FG.5 FL.1.5.1 9.8-18.7% 13.7% 10.2% 9.9% 8.4% XBB.1 16 8.6-11,9% 8.4-11.7% XBB.1.16.6 HV.1 6.6-10.5% XBB.2.3 7.2% 6.2-8.5% XBB.1.16.1 3.4-4.9% X88 1 5 70 3.8% 2.9-4.9% 2.3-3.8% XBB.1.16.11 2.5% 2.2% 1.9% 1.7% 1.5% 1.2% 0.9% 2.1-2.9% XBB XBB.1.5 60% XBB.1.9,1 1.6-2.2% GE.1 EG.6.1 1.0-2.1% 0.9-1.6% 0.5-1.7% XBB.1.5.72 40% XBB.1.42.2 X88 192 0.7% 0.6.0.9% XBB.1.5.68 0.4-0.9% 0.4-0.7% XBB.1.5.10 0.6% XBB.2.3.8 CH.1.1 FD.1.1 0.3% 0.3% 0.2% 0.2% 0.0% 0.0% 0.2-0.4% 0 2-0 4% XBB.1.5.59 0.1-0.4% 20% EU.1.1 0.0-0.1% XBB.1.5.1 0.0.0.0% BQ.1 0.0% 0.0-0.1% BA.2.12.1 B.1.1.529 0.0% 0.0-0.0% Selected 2/Weat BA.5 FD.2 0.0-0.0% 0.0% Collection date, two-week period ending

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Data from 5/28 – 9/16 2023

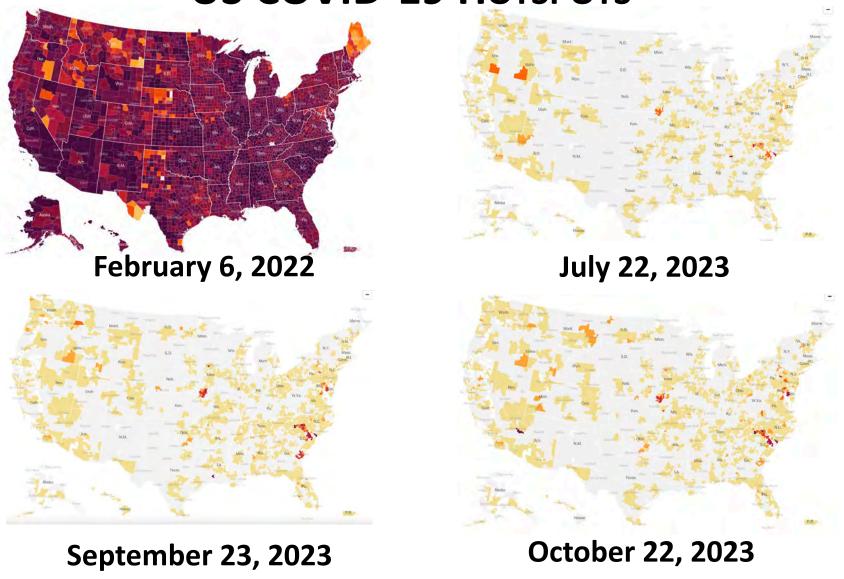
Weighted and Nowcast Estimates in United States for 2-Week Periods in 6/25/2023 – 10/14/2023

Nowcast Estimates in United States for 10/1/2023 – 10/14/2023

tover over (or tap in mobile) any lineage of interest to see the amount of uncertainty in that Nowcast: Model-based USA Weighted Estimates: Variant proportions based on reported projected estimates NHO label Linnage # %Total 95%P1 genomic sequencing results of variant 16.8-22.6% 10.8-16.7% 10.8-16.7% 3.6-6.7% 3.6-6.7% 3.4-4.9% 2.5-3.9% 2.4-3.9% 1.3-2.4% 1.3-2.4% 1.3-2.4% 1.3-2.1% 1.3-2.4% 1.3-2.1% 0.8-1.8% 0.7-1.2% 0.7-1.2% 0.6-1.2% Omicton EG.5 HV1 FL.6.5.1 FL.6.5.1 XB6.1.6.6 XB6.1.6.6 XB6.2.3 XB6.2.3 XB6.1.6.11 XB6.1.16.11 XB6.1.16.15 HF.1 XB6.1.5.70 GK.2.1 XB6.1.5.70 GK2.2 XB6.1.5.70 GK2.5 XB6.1.5.70 GK2.5 XB6.1.5.70 CH1.1.7 XB6.1.5.70 CH1.1.1 XB6.1.5.73 XB6.1.5.70 CH1.1.1 XB6.1.5.73 XB6.1.5.74 XB6.1.5.74 XB6.1.5.74 XB6.1.5.75 XB6.1.5.75 CH1.1.1 XB6.1.5.75 XB6.1.55 XB6.1.5 proportions 80% 0.6-1.2% 0.6-1.0% 0.4-0.8% 0.3-0.8% 0.4-0.7% 0.3-0.8% 0.1-0.8% 0% 6/23 XBE 1.5.1 EU 1.1 B.1.1.529 BO.1 0.0-0.0% Mark Street Other Collection date, two-week period ending and incapes are UL VOC and insegre a routining move 1's nanonary in an instruct one 2 week period. "Other" represents the approximan of it Ith BA 2 Except BA 2 752 CH 5 arm appropriate to 0A.9. E totact to X00.1.5. Except FE. Data from 6/25 – 10/14 2023

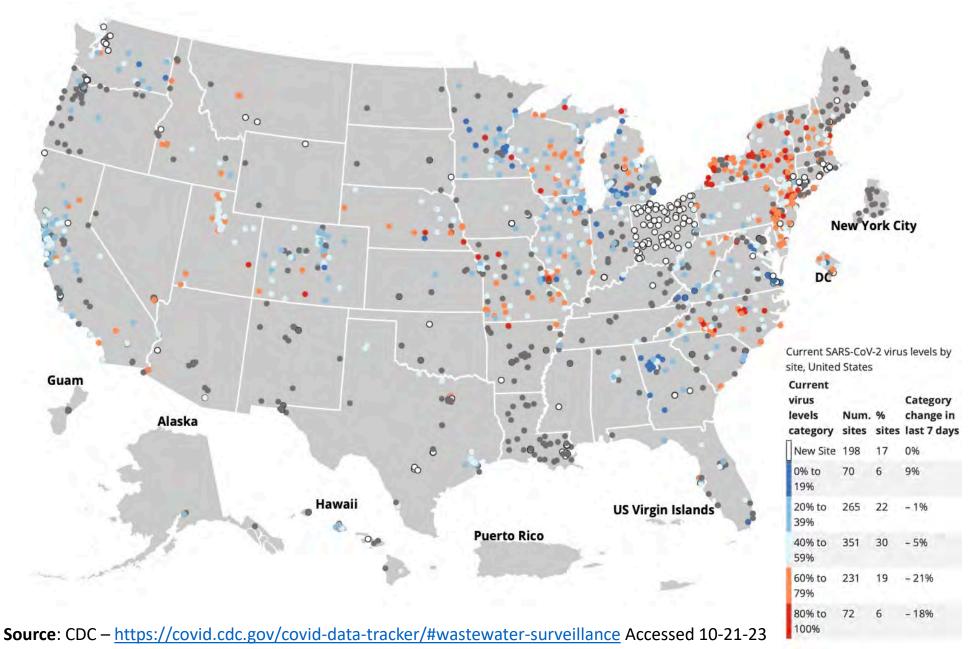
https://covid.cdc.gov/covid-data-tracker/#variant-proportions

US COVID-19 HOTSPOTS

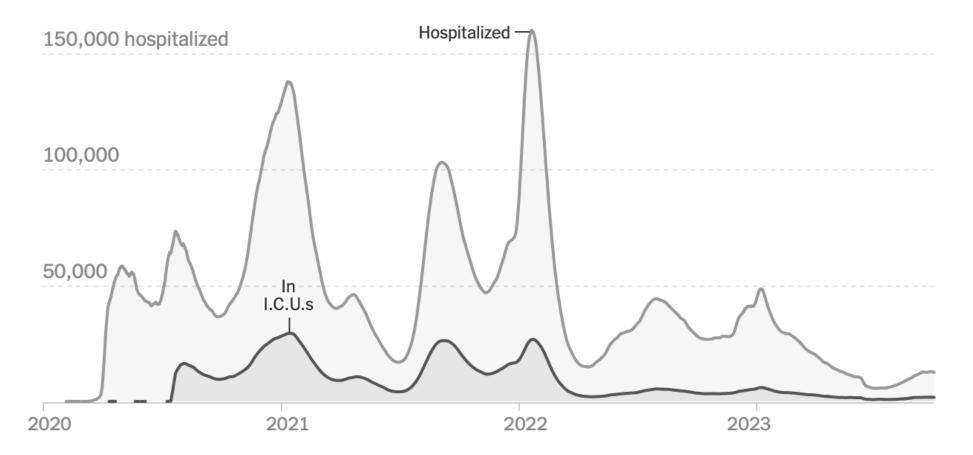


Source: New York Times <u>https://www.nytimes.com/interactive/2023/us/covid-cases.html</u> 10-21-2023

COVID-19 WASTEWATER SURVEILLANCE



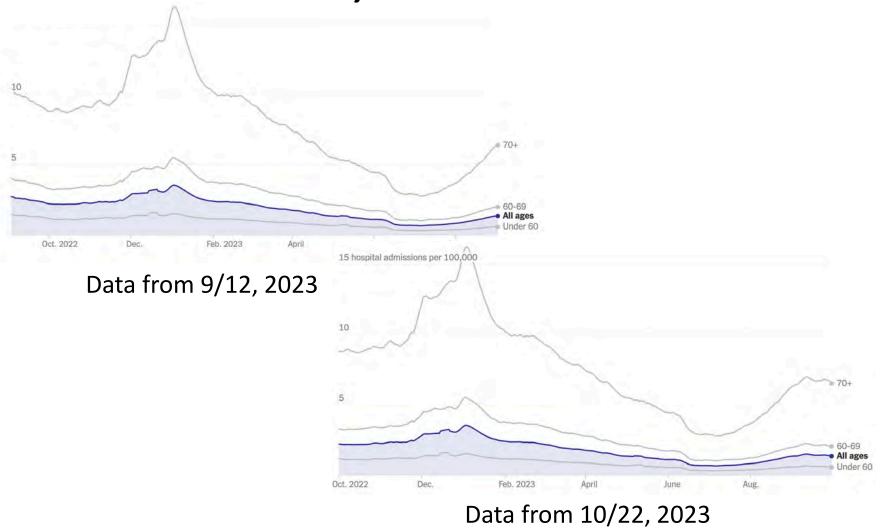
HOSPITALIZATIONS AND ICU HOSPITALIZATIONS FOR COVID-19 IN THE UNITED STATES



Hospitalizations unchanged from our last Town Hall ICU admissions decreased by 1.9% from our last Town Hall

Source: https://www.nytimes.com/interactive/2023/us/covid-cases.html accessed 10-21-23

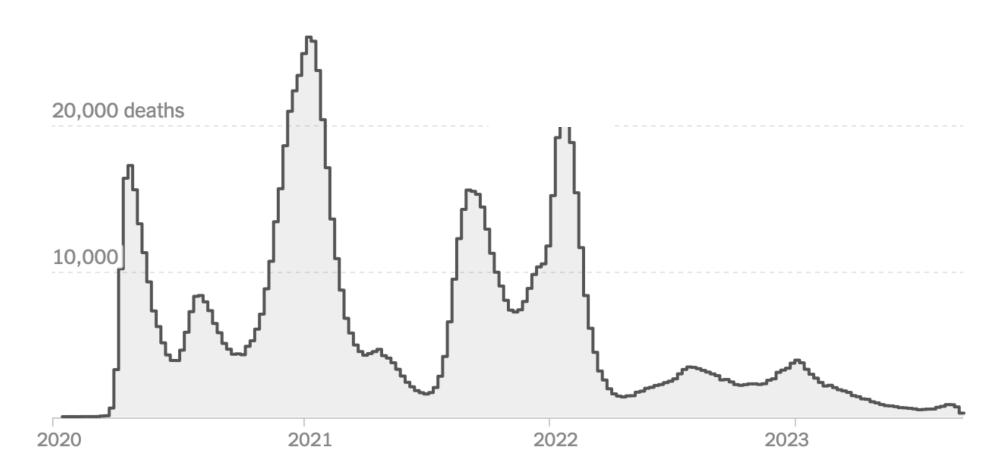
COVID-19 DAILY HOSPITAL ADMISSIONS IN THE UNITED STATES, BY AGE



Daily hospitalizations decreased by 4.5% from our last Town Hall Source: New York Times 10-21-2023

COVID-19 DEATHS IN THE UNITED STATES

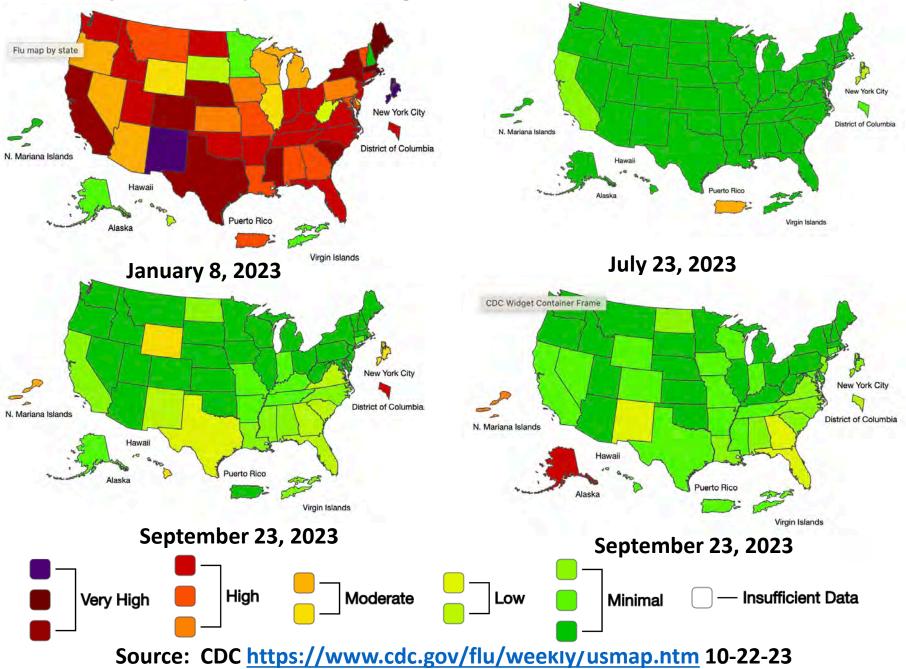
Cumulative Deaths – 1,143,192



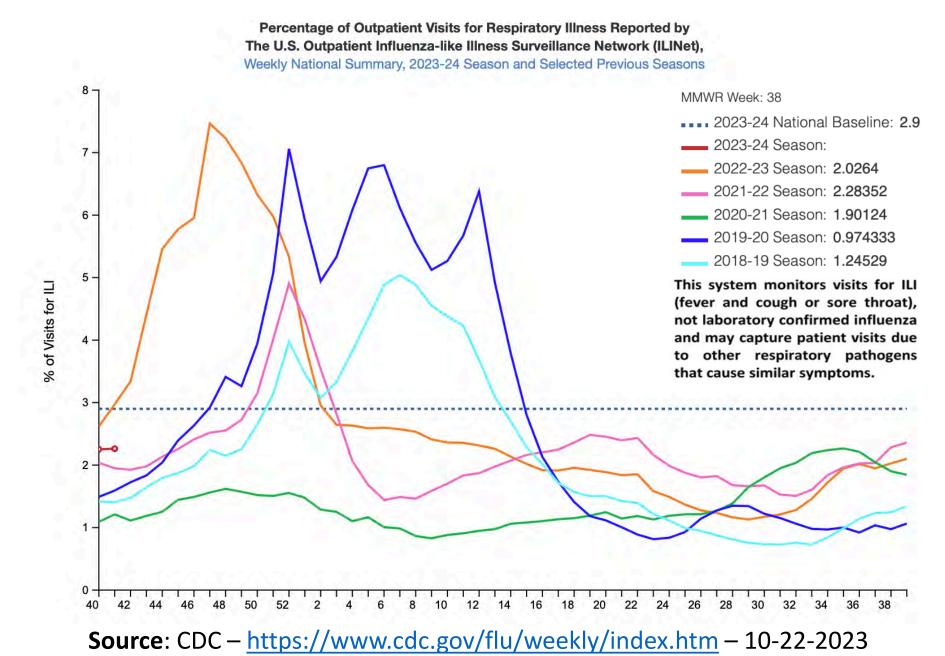
52.2% decreased from our last Town Hall

Source: NY Times https://www.nytimes.com/interactive/2023/us/covid-cases.html 10-21-23

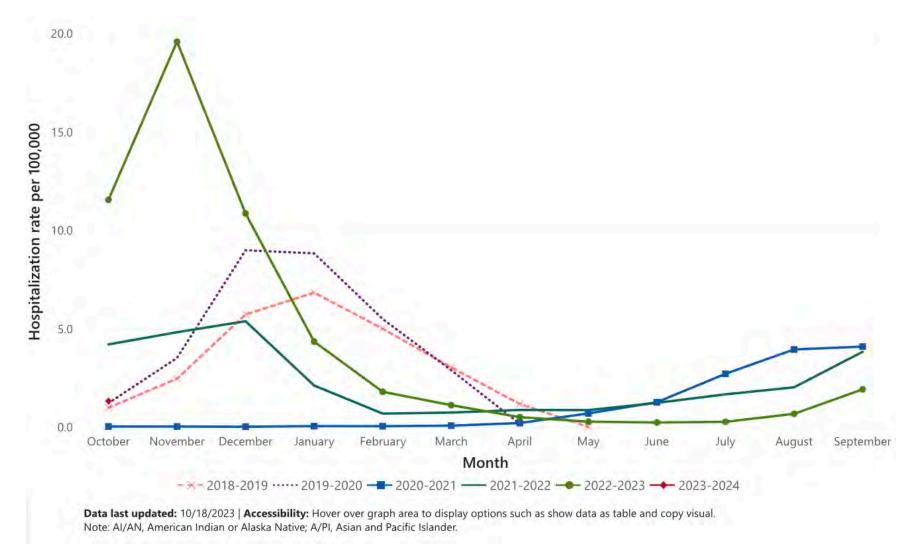
INFLUENZA ACTIVITY BY STATE IN THE I INITED STATES



PERCENTAGE OF OUTPATIENT VISITS FOR INFLUENZA-LIKE ILLNESS



HOSPITALIZATIONS FOR RESPIRATORY SYNCYTIAL VIRUS, U.S.



Source: CDC – <u>https://www.cdc.gov/rsv/research/rsv-net/dashboard.html</u> 10-21-23

This Month's Emerging Infectious Disease News

- 1. A **Nature** study demonstrated the utility of nasal swabs for assessing mucosal immune responses to SARS-CoV-2.
- 2. A randomized controlled trial published in **The New England Journal of Medicine** showed that treatment with inhaled fluticasone furoate for 14 days did not result in a shorter time to recovery than placebo among outpatients with COVID-19.
- 3. A **JAMA Network Open** study demonstrated that high-flow nasal oxygen and noninvasive ventilation appear not to be aerosol-generating procedures.
- 4. A large **JAMA Network Open** retrospective cohort study, found that COVID-19 was associated with a substantial risk for the subsequent development of autoimmune and autoinflammatory connective tissue disorders.
- 5. A **JAMA Internal Medicine** study of US Veterans found that COVID-19 survivors had no clinically significant excess hazard of death greater than comparators among those who survived at least 6 months after infection.
- 6. A *JAMA* study found that that long-term support for family members of ICU patients with COVID-19 ARDS should be the same as for relatives of patients with other causes of ARDS.
- 7. A **Lancet Public Health** paper provided a retrospective assessment of COVID surveillance systems used in England during the pandemic, concluding that deploying a suite of monitoring systems is optimal.

References available in the chat

This Month's Emerging Infectious Disease News

- 8. Another **Lancet** paper reported on the comparative effectiveness of nirmatrelvir/ ritonavir versus sotrovimab for preventing severe COVID-19 outcomes in nonhospitalized high-risk patients during Omicron, finding approximately equivalent outcomes for both.
- 9. An opinion piece in **The Journal of Infectious Diseases** presents evidence that socalled 'hybrid immunity' (i.e., vaccination plus infection) produces more robust immunity than either alone.
- 10. A paper in **Clinical Infectious Diseases** found that in a highly immune adult population, median SARS-CoV-2 viral loads peaked around the fourth day of symptoms and that Influenza A viral loads peaked soon after symptom onset.
- 11. A short **Clinical Infectious Diseases** opinion piece written by a fellow in infectious diseases describes his grieving process during the pandemic in part stimulated by his struggles with close family members who routinely reported their anti-science beliefs and conspiracy theories about COVID.
- 12. A paper in **Infection Control and Hospital Epidemiology** found that an immediate, substantial, and sustained increase of healthcare-associated respiratory viral infections occurred after the institution discontinued universal masking.
- The U.S. Food and Drug Administration amended the emergency use authorization (EUA) for the Novavax COVID-19 Vaccine, Adjuvanted to include the 2023-2024 formula for anyone 12 years of age and older.
- 14. The **NIAID** is beginning a clinical trial of a "Universal" influenza vaccine. **References available in the chat**

Panelists:



Dr. David Henderson NIH Consultant



Dr. Sarah Haessler *Baystate Health*



Dr. Kristina Bryant University of Louisville



Dr. David Weber UNC School of Medicine



SAFE HEALTHCARE FOR ALL

COVID-19 UPDATE: RISKS TO PREGNANT PERSONS AND THEIR CHILDREN & COVID-19 VACCINE AND SAFETY

David J. Weber, MD, MPH, FIDSA, FSHEA, FRSM (London) Sanders Distinguished Professor of Medicine, Pediatrics and Epidemiology Associate Chief Medical Officer, UNC-MC Medical Director, Hospital Epidemiology, UNC-MC University of North Carolina, Chapel Hill, NC



Disclosures: Consultancy; Pfizer, PDI, BD, Germitec, GAMA All drugs/vaccines issues discussed consistent with FDA approvals or authorizations

Adverse maternal, fetal, and newborn outcomes among pregnant women with SARS- CoV-2 infection: an individual participant data meta-analysis

Table 4 Relative risk of outcomes comparing COVID-19 cases (symptomatic cases only) versus COVID-negative pregnancies

Outcome	Studies (n)	Included studies*†	Symptomatic RR (95% Cl)
ICU admission	8	cde1*e21hjk	4.88 (2.57 to 9.27)
Ventilation	7	cde1*e2fhj	24.09 (6.85 to 84.77)
Critical care	7	cde1*e2fhj*	8.47 (3.37 to 21.28)
Pneumonia	6	c e1* e2 f h j*	34.58 (3.36 to 356.13
Maternal death	10	a* c* d* e1* e2* f* g h i j*	8.48 (1.70 to 42.21)
Haemorrhage	6	acghik	1.30 (0.81 to 2.10)
Placental abruption	5	afhj*k	2.08 (0.95 to 4.53)
Hypertensive disorders of pregnancy (diagnosed at or after COVID-19)		abj	1.74 (1.01 to 3.00)
Hypertensive disorders of pregnancy (diagnosed at any time)	10	abce1e2ghijk	1.28 (1.03 to 1.59)
Pre-eclampsia	9	abde1e2fijk	1.58 (1.20 to 2.08)
Eclampsia	7	a* b* e1* e2* i j* k*	1.07 (0.05 to 22.17)
Pre-eclampsia or eclampsia	10	abce1e2ghijk	1.63 (1.26 to 2.11)
Thromboembolic disease	8	a c d* e1* e2* g* i* j*	9.64 (1.69 to 54.97)
Preterm labour	6	c e1* e2 g i j	1.87 (1.06 to 3.32)
Preterm labour (COVID-19 onset <37 weeks)	4	cgij	2.71 (1.25 to 5.85)
Caesarean section	10	acde1e2ghijk	1.16 (1.04 to 1.29)
Intrapartum C-section	8	ace1*e2ghij	1.27 (1.06 to 1.52)
Stillbirth	12	abcd*e1e2fghij*k	1.35 (0.62 to 2.96)
Perinatal death	9	acdete2fgij*	1.45 (0.62 to 3.43)
Early neonatal death	9	acde1e2*fgij*	1.89 (0.61 to 5.9)
Neonatal death	10	acde1e2*fghlj*	1.93 (0.71 to 5.25)
NICU admission at birth	7	acde2fgj	2.12 (1.31 to 3.43)
Very low birth weight (<1500g)	12	abcde1e2fghij*k	1.67 (1.07 to 2.62)
Low birth weight (<2500 g)	12	abcde1e2fghijk	1.32 (1.09 to 1.59)
Small for gestational age (3rd)	12	abcde1e2fghijk	1.22 (0.86 to 1.71)
Small for gestational age (10th)	12	abcde1e2fghijk	1.05 (0.85 to 1.30)
Moderate preterm birth (<34 weeks)	12	abcde1e2fghijk	1.62 (1.20 to 2.17)
Moderate preterm birth (<34 weeks) (COVID-19 onset <34 weeks)‡	7	bcdgijk	3.12 (1.94 to 5.02)
Preterm birth (<37 weeks)	12	abcdete2fghijk	1.41 (1.15 to 1.73)
Preterm birth (<37 weeks) (COVID-19 onset <37 weeks)‡	7	bcdgijk	1.70 (1.22 to 2.36)

WHAT IS ALREADY KNOWN ON THIS TOPIC

- ⇒ Despite the ballooning literature regarding SARS-CoV-2 infection during pregnancy, it is difficult to synthesise the information and evaluate the overall quality of evidence given the heterogeneity in study design, selection of comparison groups, methods for assessing infection, population-specific baseline risks and definitions of key outcomes.
- ⇒ Prior reviews based on published data have included limited data from low-income countries.

WHAT THIS STUDY ADDS

- ⇒ We established plans for a sequential, prospective meta-analysis in April 2020 with a goal of better understanding the excess risks—or lack thereof—of COVID-19 during pregnancy.
- This individual patient data meta-analysis of unpublished and published data from a dozen studies includes more than 13000 pregnant women and shows that COVID-19 during pregnancy increases the risk of maternal mortality, intensive care unit admission, receiving mechanical ventilation, receiving any critical care or being diagnosed with pneumonia or thromboembolic disease.
- Infants born to infected pregnant women were more likely to be admitted to the neonatal intensive care unit and to be born premature.
- ⇒ In contrast to other reviews, we did not find any link between SARS-CoV-2 infection during pregnancy and an increased risk of stillbirth at or beyond 28 weeks' gestation, nor any link with intrauterine growth restriction.
- ⇒ Further, we include the first large set of pregnancy cohort data from sub-Saharan Africa.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

- ⇒ Global guidance has been equivocal on the potential risks of infection and benefits and safety of vaccination, and more than 80 countries do not currently recommend that all pregnant and lactating women should be vaccinated.
- ⇒ Given the clear and consistent findings regarding the risk of COVID-19 infection during pregnancy, global effort to improve access to safe preventives and therapeutics is an urgent priority.

Smith ER, et al BMJ Global Health 2023;8:e009495

Comparison of Maternal and Neonatal Outcomes between SARS-CoV-2 Variants: A Retrospective, Monocentric Study

This retrospective, monocentric study aimed to fill this knowledge gap by analyzing the outcomes of pregnant women with acute SARS-CoV-2 infection caused by the Alpha, Delta, and Omicron variants. The study, conducted between December 2020 and March 2022 at San Marco Hospital, included 313 pregnant women with confirmed SARS-CoV-2 infection. The results showed that the Delta variant was associated with a significantly higher incidence of adverse outcomes, such as premature births, maternal intensive care unit admission, intrauterine growth restriction, and small for gestational age infants. Additionally, the Delta variant was linked to lower Apgar scores, higher maternal and fetal mortality rates, and increased levels of various biomarkers indicating more severe illness. Finally, the Delta variant also presented a greater possibility of vertical transmission.

	Alpha Group (n = 104)	Delta Group (n = 55)	Omicron Group (n = 154)	p-Value
CRP (mg/L)	56.93 ± 20.12	107.13 ± 40.34	59.51 ± 21.46	< 0.001
PCT (ng/mL)	0.20 ± 0.08	6.47 ± 2.51	0.22 ± 0.09	< 0.001
IL-6 (pg/mL)	30.21 ± 10.13	339.54 ± 100.51	24.13 ± 9.31	< 0.001
Hb (g/dL)	11.15 ± 1.51	9.79 ± 1.85	11.59 ± 1.45	< 0.001
Leukocytes (n/mm ³)	10.38 ± 2.13	10.89 ± 2.34	10.95 ± 2.28	0.572
Neutrophil (%)	74.15 ± 6.31	79.66 ± 7.24	78.55 ± 6.91	0.061
Lymphocyte (%)	15.32 ± 4.51	17.57 ± 5.12	15.86 ± 4.73	0.032
D-dimer (ng/mL)	1257.31 ± 401.13	1594.58 ± 510.67	1279.79 ± 412.37	0.001
AST (U/L)	54 ± 15.32	100 ± 30.13	59 ± 16.42	< 0.001
ALT (U/L)	61 ± 17.32	116 ± 33.46	65 ± 18.23	< 0.001
Maternal admission to ICU (n)	0	9	2	0.002
Maternal mortality (%)	0.0	1.8	0.0	0.049
Neonatal weight (grams)	3252 ± 412.32	2533 ± 513.62	3161 ± 402.18	< 0.001
Apgar score at 1st min	8.84 ± 1.13	8.18 ± 1.41	8.75 ± 1.19	< 0.001
Apgar score at 5th min	9.84 ± 0.67	9.26 ± 0.88	9.80 ± 0.71	< 0.001
Neonatal mortality (%)	0.0	5.5	0.0	0.001
Vertical transmission (%)	5.0	20.0	7.0	< 0.001

Table 2. Biochemical data and maternal-neonatal outcomes.

Abbreviations: ALT: alanine aminotransferase; AST: aspartate aminotransferase; CRP: C-reactive protein; Hb: hemoglobin; ICU: intensive care unit; IL-6: interleukin 6; n: number; %; PCT: procalcitonin. Continuous variables are expressed as mean \pm standard deviations (SD) and categorical variables were summarized as percentages.

Incognito GG, et al. J Clin Med 2023;12:6329

SARS-CoV-2 infection and COVID-19 vaccination in pregnancy

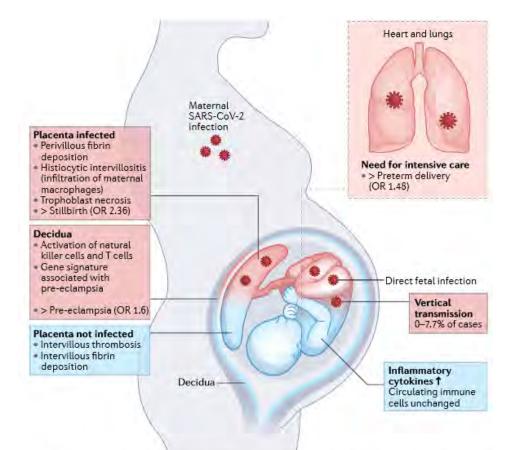


Fig. 1 | Direct versus indirect effects of SARS-CoV-2 infection on the fetus and placenta. Maternal SARS-CoV-2 infection can impact pregnancy in numerous ways. The need for intensive care associated with severe disease can necessitate delivering the infant, causing an increased rate of preterm delivery. Placental infection can be associated with SARS-CoV-2 placentitis, which is associated with an increased risk of stillbirth. Even in the absence of placental infection, inflammatory changes are observed in the decidua and placenta, and these may be linked to the increased risk of pre-eclampsia associated with SARS-CoV-2 can also be vertically transmitted to infect the fetus, although this is uncommon. Blue indicates indirect outcomes on the fetus and placenta associated with SARS-CoV-2, whereas red indicates outcomes associated with direct fetal infection.

Study	Number of participants vaccinated in pregnancy	Country	Approach	Outcomes examined	Impact of COVID-19 vaccination	Ref.	
v-safe pregnancy registry	5,096	United States	Registry	Stillbirth, preterm birth (PTB), small for gestational age (SGA), neonatal death, congenital abnormalities	None detected	35	
				PTB, SGA, neonatal intensive care unit (NICU) admission, neonatal death, congenital abnormalities	None detected		
				Miscarriage	None detected	43	
BORN Ontario	64,234	Canada	Registry	PTB, stillbirth, SGA	None detected	-11	
Stock et al., 2022	ck et al., 2022 18,399		Registry	PTB, perinatal death	None detected		
Bookstein-Peretz 390 et al., 2021		Israel	Registry	Miscarriage, PTB, SGA, NICU admission	None detected		
Norwegian National Health Registries	1,003	Norway	Case control	Miscarriage	None detected	147	
Vaccine Safety Datalink	31,080	USA	Case-control	Stillbirth	None detected	45	
				Miscarriage	None detected		
			Cohort	PTB, SGA	None detected	day	
Wainstock et al., 2021	913	Israel	Cohort	PTB, pre-eclampsia, SGA	None detected	-40	
Blakeway et al., 2021	akeway et al., 2021 140		Cohort	PTB, stillbirth, SGA, NICU admission, congenital abnormalities	None detected	51	
Maccabi Healthcare Services	24,288	Israel	Cohort	Miscarriage, PTB, stillbirth, pre-eclampsia, SGA, SARS-CoV-2 infection	Reduced risk of SARS-CoV-2 infection	57	
			Cohort	PTB, SGA, congenital abnormalities, death and hospitalization of infants up to 6 months old	None detected	50	
Theiler et al., 2021	140	United States	Cohort	PTB, stillbirth, pre-eclampsia, SGA, NICU admission, SARS-CoV-2 infection	Reduced risk of SARS-CoV-2 infection	53	
UK Health Security Agency	58,165	United Kingdom	Cohort	PTB, stillbirth, SGA	None detected		

Results from the 12 studies summarized show no increased risk of any poor obstetric outcome associated with COVID-19 vaccination. The total number of participants included in these studies is 185,309. This has been calculated as the sum of all participants, except for those in Blakeway et al.⁵¹ and Stock et al.⁸, who are also included in the UK Health Security Agency data and would otherwise be counted twice.

Male V. Nature Reviews, Immunology: 2022;22:277

THE REPORT OF TH

An Update on COVID-19 Vaccination and Pregnancy

Main Benefits of COVID-19 Vaccination in Pregnancy	Main Risks of COVID-19 Vaccination in Pregnancy			
Reduction in the risk of SARS-CoV-2 infection	Injection site pain			
[10,25,38-45]	[24,25]			
Reduction in the risk of severe SARS-CoV-2 infection	Fever			
[25,38-44,46,47]	[24,25]			
Reduction in the risk of COVID-19-related hospitalization	Rash			
[10,25,38-45,47]	[24,25]			
Reduction in the risk of ICU admission	Fatigue			
[25,38–44,47]	[24,25]			
Reduction in the risk of maternal mortality	Arthralgia			
[25,38–44]	[24,25]			
Decrease in stillbirth	Myalgia			
[1,38,39,48]	[24,25]			
Decrease in total preterm births	Headache			
[43,48,49]	[24,25]			
Reduction in the risk of SARS-CoV-2 infection in infants <6 months	Nausea or vomiting			
[50,51]	[24,25]			
Reduction in the risk of severe SARS-CoV-2 infection in infants, including MIS-C [3,52]	Chills [24,25]			
Reduction in the risk of hospitalization for COVID-19 in infants <6 months [17,25,40,43,53,54]	Lymfadenopathy [24,25]			
Reduction in the risk of ICU admission in infants <6 months [3]	Lymfadenithis [24,25]			

Julia-Burches C, Marinez-Varea A. J Personalized Med 2023;May



A population-based test-negative matched case control analysis of SARS-CoV-2 vaccine effectiveness among pregnant people in Ontario, Canada

Methods: Population-based matched test-negative casecontrol study of pregnant people aged 18–49 years, of 12 or more weeks' gestation in Ontario, Canada, symptomatic with possible SARS-CoV-2 infection, and having at least one positive (n = 1842) or negative (n = 8524) rRT-PCR SARS-CoV-2 test between December 14, 2020 and December 31, 2021.

Results: In the primary outcome analysis, there were 1821 positive cases, matched to 1821 negative controls. The mean (SD) maternal age was 31 (5) years. When compared to those unvaccinated, receipt of \geq 1 dose was associated with an estimated VE of 39% (95% Cl 29– 48%) for symptomatic infection, and 85% (95% Cl 72– 92%) for COVID-19 hospitalization. Vaccine effectiveness estimates demonstrated waning with increased time since last vaccination.

	Exposure Status	Test-negative controls, n (%)	Test-positive cases, n (%)	aOR (95% CI)	p-value	VE ^b (95% CI)
Binary exposure	Unvaccinated	947 (52.0%)	1,123 (61.7%)	[referent]	[referent]	[referent]
	≥ 1 doseª			0.61 (0.52;		
		874 (48.0%)	698 (38.3%)	0.71)	<.0001	39 <mark>% (</mark> 29 - 48%)
6-level	Unvaccinated		$\overline{\mathbf{X}}$	[referent]	[referent]	[referent]
exposure		947 (52.0%)	1,123 (61.7%)			
	1 dose			0.53 (0.38;		
		90 (4.9%)	62 (3.4%)	0.75)	0.0003	47% (25 - 62%)
	>1 dose <2 months			0.39 (0.29;		
		158 (8.7%)	83 (4.6%)	0.53)	< 0.0001	61% (47 - 71%)
	>1 dose 2<4			0.53 (0.39;		
	months	128 (7.0%)	90 (4.9%)	0.71)	< 0.0001	47% (29 - 61%)
	>1 dose 4<6			0.71 (0.58;		
	months	344 (18.9%)	321 (17.6%)	0.86)	0.0004	29% (14 - 42%)
	>1 dose >6 months			0.72 (0.55;		
		154 (8.5%)	142 (7.8%)	0.93)	0.0122	28% (7.0 - 45%)
2. Secondary	outcome analysis (sever	re COVID-19 illness)			
	Exposure Status	Non-	Hospitalized	aOR (95% CI)	p-value	VE ^a (95% CI)
		hospitalized controls, n (%)	cases, n (%)			
Binary	Unvaccinated	239 (57.5%)	93 (89.4%)	[referent]	[referent]	[referent]
exposure	≥ 1 doseª			0.15 (0.0, 0.2)	<0.0001	050/ (70 000/)
	≥ 1 dose	177 (42.5%)	11 (10.6%)	0.15 (0.0; 0.2)	<0.0001	85% (72 - 92%)

Associations of COVID-19 vaccination during pregnancy with adverse neonatal and maternal outcomes: A systematic review and meta-analysis

Forty-three observational studies were included. COVID-19 vaccination [96,384 (73.9%) BNT162b2, 30,889 (23.7%) mRNA-1273, and 3,172 (2.4%) other types] during pregnancy [23,721 (18.3%) in the first trimester, 52,778 (40.5%) in the second trimester, and 53,886 (41.2%) in the third trimester],was associated with reduced risks of stillbirth or neonatal death (OR, 0.74; 95% CI, 0.60–0.92). COVID-19 vaccination during pregnancy was not associated with congenital anomalies (OR, 0.83; 95% CI, 0.63–1.08), preterm birth (OR, 0.98; 95% CI, 0.90–1.06), NICU admission or hospitalization (OR, 0.94; 95% CI, 0.84–1.04), an Apgar score at 5 min <7 (OR, 0.93; 95% CI, 0.86–1.01), low birth weight (OR, 1.00; 95% CI, 0.88–1.14), miscarriage (OR, 0.99; 95% CI, 0.88–1.11), cesarean delivery (OR, 1.07; 95% CI, 0.96–1.19), or postpartum hemorrhage (OR, 0.91; 95% CI, 0.81–1.01).

	Vaccin	ated	Unvacc	inated		Odds Ratio	Odds Ratio
study or Subgroup	Events	Total	Events	Total	Weight	IV, Random, 95% CI	CI IV. Random, 95% CI
Blakeway et al,17 2022	0	133	1	399	0.4%	1.00 [0.04, 24.57]) (
Dick et al.21 2022	20	2305	33	3313	14.8%	0.87 [0.50, 1.52]	
Soldshtein et al. ²⁰ 2021	1	7530	2	7530	0.8%	0.50 (0.05. 5.51)	i +
Agnus et al,29 2022	50	28506	338	129015	52,2%	0.67 (0.50, 0.90)	-8-
Rottenstreich et al. 2022	5	712	5	1073	3.0%	1.51 [0.44, 5.24]	
Stock et al.12 2022	25	5766	427	76690	28.2%	0.78 [0.52, 1,17]	
Theiler et al, [™] 2021	0	140	6	1862	0.6%	1.02 (0.06, 18.13))
otal (95% CI)		45092		219882	100.0%	0.74 [0.60, 0.92]	•
otal events	101		612			OCCURATE AN	
Heterogeneity: Tau ³ = 0.00;	Chi ² = 2.2	7, df = 6	(P = 0.89	9); I ² = 0%			
est for overall effect. Z = 2.				M			0.05 0.2 1 5 20
est for overall effect: $Z = Z$.	69 (P = 0.	007)					Favours [Vaccine] Favours [Control]

Ding C, et al. Front Public Health, 2023; Jan



Safety of COVID-19 vaccines during pregnancy: A systematic review and meta-analysis

Results: Among non-COVID-19 vaccines, the most frequent exposures were AS03 and aluminum-based adjuvants. A meta-analysis of studies that adjusted for potential confounders showed no association with adverse outcomes, regardless of the vaccine or the trimester of vaccination. Neither the reported rates of adverse pregnancy outcomes nor reactogenicity exceeded expected back-ground rates, which was the case for ASO3- or aluminum-adjuvanted non-COVID-19 vaccines in the proportion meta-analyses of uncontrolled studies/arms. The only exception was postpartum hemorrhage after COVID-19 vaccination (10.40%; 95% CI: 6.49–15.10%), reported by two studies; however, the comparison with non-exposed pregnant persons, available for one study, found non-statistically significant differences (adjusted OR 1.09; 95% CI 0.56–2.12). Animal studies showed consistent results with studies in pregnant persons.

(A) Global low risk of bias

Conclusion: We found no safety concerns for currently administered COVID-19 vaccines during pregnancy.

Study or Subgroup	log[Odds Ratio]	SE	COVID-19 vaccine Total	No COVID-19 vaccine Total	Odds Ratio Random, 95% C	Odds Ratio IV. Random, 95% Cl	Rtsk of Bias	
1.1 Abortion (spont	taneousor induce	d)						
Goldshtein 2021 1.2 Stillbirth	0.0827	0.1287	7530	7530	1.09 [0.84, 1.40]		•	
Goldshtein 2021 1.3 Congenital mail		1.2251	7530	7530	0.50 [0.05, 5.52		•	
Blakeway 2021	-0.1165	0.6687	133	399	0.89 [0.24, 3.30]			
1.4 Preterm birth								
Goldshlein 2021	-0.0999	0.1582	7530	7530	0.90 (0.66, 1.23)			
1.5 Small for gesta	tional age							
Blakeway 2021	0	0.305	133	399	1.00 [0.55, 1.82			
1.6 Fetal growth re	striction							
Goldshtein 2021		0.2332	7530	7530	0.95 (0.60, 1.50)			
1.7 Preeclampsia								Ciapponi A, et al. Vaccine 2023;41:3688
Goldshtein 2021	-0.0489	0.3128	7530	7530	0.95 [0.52, 1.76]	-		
1.8 Postpartum he	morritage					T.		
Blakeway 2021	0.0862	0.3398	133	399	1.09 (0.56, 2.12)		•	
						0.001 0.1 10 Favours COVID-19 vaccines Favours No COVID-	1000 19 vaccines	

Fig. 2. Forest plots of pregnancy outcomes comparing exposure with no exposure to COVID-19 vaccines.

The impact of COVID-19 vaccines on fertility: A systematic review and meta-analysis

Methods: PubMed, Scopus, Web of Science, Cochrane and Embase databases were searched for eligiblestudies until June 8th, 2022. The search was restricted to articles regarding humans, published in any languages, without additional restrictions

Results: Out of 1406 studies screened, 29 were included in the systematic review. These studies, conducted in Israel (34.5 %), USA (24.1 %), Russia (20.7 %) China (10.3 %), Italy (3.5 %), North America (3.5%) and Turkey (3.5 %) were of poor (34.5 %), moderate (58.6 %) and good (6.9 %) quality. Meta-analyses were performed for pre- and post-vaccination sperm progressive motility (44 %, 95 % CI 42 %-62 % vs 43 %, 95 % CI 31 %-59 % p = 0.07) and concentration (50.6 mln/ml, 95 % CI 35.1–72.8 vs 55.4 mln/ml, 95 % CI 37.4–82.2p = 0.12). Biochemical (0.51, 95 % CI 0.40–0.66 vs 0.60, 95 % CI 0.53–0.68p = 0.45) and clinical (0.45, 95 % CI 0.37–0.54 vs 0.47, 95 % CI 0.40–0.55 p = 0.31) pregnancy rate did not differ among vaccinated and not vaccinated groups. Subgroup meta-analyses based on the type of vaccine showed no significant difference: between vaccinated with mRNA vaccines and non-vaccinated regarding biochemical pregnancy rates; pre- and post-vaccination with Gam-COVID-Vac regarding testosterone, FSH and LH levels; pre- and post-vaccination with BNT162b2 vaccines regarding sperm volumes.

Conclusion: Based on the studies published so far, there is no scientific proof of any association between COVID-19 vaccines and fertility impairment in men or women.

Zace D, et al. Vaccine 2022;40:6023-6034



ACOG: COVID-19 Vaccines and Pregnancy: Conversation Guide

- The American College of Obstetricians and Gynecologists (ACOG) strongly recommends that pregnant individuals be vaccinated against COVID-19.
- Vaccination may occur in any trimester, and emphasis should be on vaccine receipt as soon as possible to maximize maternal and fetal health.
- For patients who do not receive any COVID-19 vaccine, the discussion should be documented in the patient's medical record. During subsequent office visits, obstetrician–gynecologists should address ongoing questions and concerns and offer vaccination again.
- COVID-19 vaccines may be administered simultaneously with other vaccines, including within 14 days of receipt of another vaccine. This includes vaccines routinely administered during pregnancy, such as the influenza and Tdap vaccines.

https://www.acog.org/covid-19/covid-19-vaccines-and-pregnancy-conversation-guide-for-clinicians



ACOG: COVID-19 Vaccines and Pregnancy: Key Messages

Risk Associated With COVID-19 Infection During Pregnancy

- COVID-19 infection during pregnancy is associated with increased risk of maternal severe illness, admission to an intensive care unit, mechanical ventilation, and death. There is increased risk of infection and death for certain racial and ethnic populations.
- There is a known increased risk of complications from COVID-19 in pregnant patients with underlying health conditions (e.g., diabetes, obesity, increasing age, and cardiovascular disease).
- There is an increased risk of preterm delivery, and there may be an increased risk of stillbirth.

Safety of COVID-19 Vaccines

- None of the COVID-19 vaccines available for use under emergency use authorization or U.S. Food and Drug Administration (FDA) license causes infertility or spontaneous abortion.
- There is no evidence of adverse maternal or fetal effects from vaccinating pregnant individuals with the COVID-19 vaccine, and a growing body of data demonstrates the safety of such use.

Efficacy of COVID-19 Vaccines

- The effectiveness of COVID-19 vaccines is similar in pregnant and non-pregnant individuals of similar age for prevention of COVID-19 infection and hospitalizations.
- All currently available COVID-19 vaccines have demonstrated high efficacy among their respective clinical trial endpoints.

Safety and Efficacy for the Newborn

• There are accumulating data demonstrating that antibodies are passed to the fetus when a pregnant person is vaccinated. gG antibodies after maternal vaccination in the third trimester have been shown in observational studies.

https://www.acog.org/covid-19/covid-19-vaccines-and-pregnancy-conversation-guide-for-clinicians



COVID-19 Vaccines While Pregnant or Breastfeeding, CDC, 9/22/23

- People who are pregnant are more likely to get very sick from COVID-19 compared to people who are not pregnant. People who get very sick from COVID-19 may require hospitalization, intensive care, or the use of a ventilator or special equipment to breathe.
 Severe COVID-19 illness can also lead to death. At increased risk of complications that can affect your pregnancy and developing baby. For example, COVID-19 during pregnancy increases the risk of delivering a preterm or stillborn infant.
- Vaccination remains the best protection against COVID-19-related hospitalization and death. Getting the updated <u>COVID-19 vaccine</u> can <u>protect you and others</u> and is important to keep you and your developing baby as healthy as possible during pregnancy.
- CDC recommends everyone ages 6 months and older get the updated COVID-19 vaccine. This includes people who are pregnant, breastfeeding, trying to get pregnant now, or those who might become pregnant in the future.
- Studies including hundreds of thousands of people around the world show that COVID-19 vaccination before and during pregnancy is safe, effective, and beneficial to both the pregnant person and the baby. The benefits of receiving a COVID-19 vaccine outweigh any potential risks of vaccination during pregnancy.
- Data show that mRNA COVID-19 vaccines during pregnancy are effective. They reduce the risk of severe illness and other health effects from COVID-19 for people who are pregnant. COVID-19 vaccination might also help prevent stillbirths and preterm delivery.
- Receiving mRNA COVID-19 vaccines during pregnancy can help protect babies younger than age 6 months from hospitalization due to COVID-19.

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html



Influenza, Tdap, and COVID-19 Vaccination Coverage and Hesitancy Among Pregnant Women, US, April 2023

Summary

What is already known about this topic?

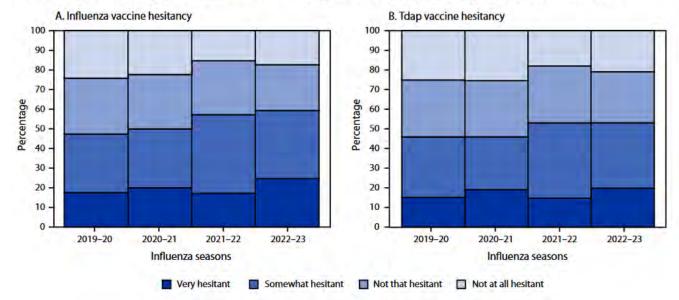
Influenza, tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap), and COVID-19 vaccines can reduce the risk for severe respiratory illness among pregnant women and their infants.

What is added by this report?

During the 2022–23 influenza season, 47.2% of women received influenza vaccination before or during pregnancy, 55.4% of women with a recent live birth received Tdap vaccination during pregnancy, and 27.3% of women received a COVID-19 bivalent booster vaccine before or during pregnancy. Pregnant women who received a provider recommendation for vaccination were less hesitant about influenza and Tdap vaccines.

What are the implications for public health practice?

Promotion of efforts to improve vaccination coverage among pregnant women, such as provider recommendation for vaccination and informative conversations with patients to address vaccine hesitancy, could reduce adverse maternal and infant illness and death from vaccine-preventable diseases. FIGURE. Percentage of pregnant women* who were hesitant⁺ about receiving influenza vaccine (A) and tetanus toxold, reduced diphtheria toxold, and acellular pertussis vaccine (B) — Internet panel survey, United States, 2019–20 through 2022–23 Influenza seasons



Razzaghi H, et al. MMWR 2023;72:1065

Inequities in COVID-19 Vaccination Coverage Among Pregnant Persons, by Disaggregated Race and Ethnicity MA, May 2021–October 2022

Summary

What is already known about this topic?

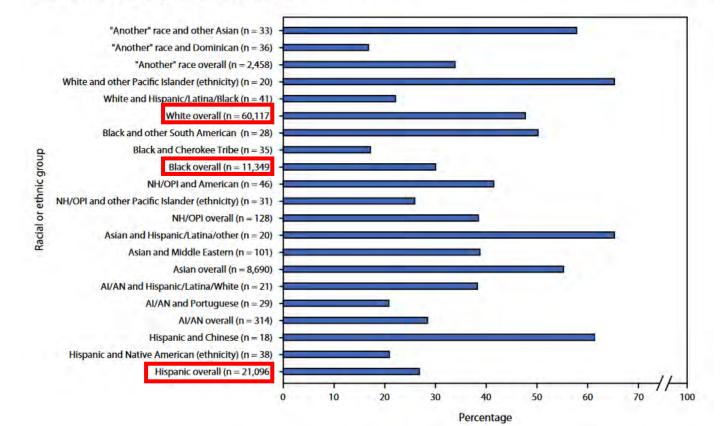
Among pregnant persons in the United States, Hispanic or Latino (Hispanic) and non-Hispanic Black or African American persons experience the highest COVID-19 rates and the lowest COVID-19 vaccination coverage. Aggregation of race and ethnicity data can obscure within-group diversity and inequities.

What is added by this report?

Among 102,275 Massachusetts residents with pregnancies resulting in live birth during May 2021–October 2022, data disaggregation into 12 racial and 34 ethnic groups revealed inequities in COVID-19 vaccination coverage that were masked within all larger race and ethnicity groupings.

What are the implications for public health practice?

Disaggregating race and ethnicity data can uncover withingroup differences in COVID-19 vaccination coverage that might guide tailored public health messaging. FIGURE 2. COVID-19 vaccination coverage* before or during pregnancy, by race and ethnicity (large groupings overall and racial and ethnic subgroups with highest and lowest rates of coverage within these large groupings)^{†,§,¶,***,††,§§,¶¶,***,^{†††} among pregnancies resulting in live birth — Massachusetts, May 1, 2021–October 31, 2022}



Shephard MH, et al. MMW:2023;72:1052 (29 Sept)

COVID-19 Vaccination Recommendations and Practices for Women of Reproductive Age by HCP, Fall DocStyles Survey, US, 2022

Summary

What is already known about this topic?

COVID-19 vaccination is recommended for all persons ≥6 months of age. Pregnant women are at increased risk for severe COVID-19 compared with other reproductive-aged women. Health care provider (HCP) recommendations are important for increasing vaccination coverage.

What is added by this report?

Although most (82.9%) surveyed HCPs recommended that women of reproductive age stay up to date with COVID-19 vaccines, only 54.7% offered or administered the vaccine in their practice. HCPs were more likely to offer or administer COVID-19 vaccination on-site to pregnant patients if they also offered or administered influenza (adjusted prevalence ratio [aPR] = 5.5) and tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) vaccines (aPR = 2.3).

What are the implications for public health practice?

Encouraging HCPs to recommend, offer, and administer COVID-19 vaccines along with influenza or Tdap vaccines might help reinforce vaccine confidence and increase coverage among women of reproductive age, including pregnant women.

TABLE 3. Factors associated with recommending and offering or administering COVID-19 vaccination on-site to pregnant patients among	
health care providers caring for pregnant patients (N = 1,538) — Fall DocStyles, United States, 2022	

	'		t pregnant patien /ID-19 vaccine	ts	Off	Offer or administer COVID-19 vaccination on-site to pregnant patients				
	No.	. (%)	PR (9	PR (95% CI)		. (%)	PR (9	PR (95% CI)		
Characteristic	Yes	No	Unadjusted	Adjusted*	Yest	No [†]	Unadjusted	Adjusted*		
Provider type					1. Carl	1.5.7.05				
FP or internist	763 (82.1)	166 (17.9)	Ref	Ref	519 (55.9)	410 (44.1)	Ref	Ref		
Pediatrician	137 (88.4)	18 (11.6)	11(10-11)	11(10-11)	103 (66 5)	52 (33.6)	12(10-13)	12(11-13)		
Ob-gyn	228 (94.2)	14 (5.8)	1.1 (1.1-1.2)	1.1 (1.1-1.2)	96 (39.7)	146 (60.3)	0.7 (0.6-0.8)	0.7 (0.6-0.9)		
NP or PA	147 (69.3)	65 (30.7)	0.8 (0.8–0.9)	0.9 (0.8-0.9)	104 (49.1)	108 (50.9)	0.9 (0.8–1.0)	0.8 (0.7-1.0)		
No. of years practic	ing									
3-10	475 (83.6)	93 (16.4)	1.0 (1.0-1.1)	0.9 (0.9-1.0)	328 (57.8)	240 (42.3)	1.2 (1.1-1.4)	0.9 (0.8-1.1)		
11-19	343 (83.9)	66 (16.1)	1.0 (1.0-1.1)	1.0 (0.9-1.0)	227 (55.5)	182 (44.5)	1.2 (1.0-1.3)	0.9 (0.8-1.1)		
≥20	457 (81.5)	104 (18.5)	Ref	Ref	267 (47.6)	294 (52.4)	Ref	Ref		
Provider age, yrs										
<50	810 (84.7)	146 (15.3)	Ref	Ref	557 (58.3)	399 (41.7)	Ref	Ref		
≥50	465 (80.0)	117 (20.1)	0.9 (0.9-1.0)	0.9 (0.9-1.0)	265 (45.5)	317 (54.5)	0.8 (0.7-0.9)	0.8 (0.6-0.9)		
Provider gender [§]										
Female	533 (84.1)	101 (15.9)	1.0 (1.0-1.1)	1.0 (0.9-1.1)	338 (53.3)	296 (46.7)	1.0 (0.9-1.1)	1.0 (0.9-1.1)		
Male	731 (82.1)	159 (17.9)	Ref	Ref	477 (53.6)	413 (46.4)	Ref	Ref		
Recommend influe	nza vaccine to pred	nant patients								
Yes	1,236 (90.0)	139 (10.1)	3.8 (2.9-4.9)	3.7 (2.8-4.9)	773 (56.2)	602 (43.8)	1.9 (1.5-2.4)	1.8 (1.4-2.3)		
No	39 (23.9)	124 (76.1)	Ref	Ref	49 (30.1)	114 (69.9)	Ref	Ref		
Recommend Tdap v	accine to pregnant	patients								
Yes	1,078 (89.8)	123 (10.2)	1.5 (1.4-1.7)	1.5 (1.4-1.7)	674 (56.1)	527 (43.9)	1.3 (1.1-1.5)	1.3 (1.1-1.4)		
No	197 (58.5)	140 (41.5)	Ref	Ref	148 (43.9)	189 (56.1)	Ref	Ref		
Offer or administer	Influenza vaccine t	o pregnant path	ents			and the second second				
Yes	1,095 (88.2)	146 (11.8)	1.5 (1.3-1.6)	1.4 (1.3-1.6)	788 (63.5)	453 (36.5)	5.5 (4.0-7.6)	5.5 (4.0-7.6)		
No	180 (60.6)	117 (39.4)	Ref	Ref	34 (11.5)	263 (88.6)	Ref	Ref		
Offer or administer	Tdap vaccine to pre	anant patients				1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1				
Yes	981 (88.7)	125 (11.3)	1.3 (1.2-1.4)	1.3 (1.2-1.4)	702 (63.5)	404 (36.5)	2.3 (2.0-2.7)	2.3 (1.9-2.7)		
No	294 (68.1)	138 (31.9)	Ref	Ref	120 (27.8)	312 (72.2)	Ref	Ref		

Abbreviations: FP = family practitioner; NP = nurse practitioner; Ob-gyn = obstetrician-gynecologist; PA = physician assistant; PR = prevalence ratio; Ref = referent group; Tdap = tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine.

* Adjusted for number of years practicing, provider age, and provider gender.

[†] Percentages might not sum to 100 because of rounding.

[§] Four health care providers were excluded from gender-stratified analyses because when asked their gender, they did not report male or female but instead responded "prefer to self-identify"; therefore, the denominator for gender is 1,534.

Meghani M, et al. MMWR 2023;72:1045 (29 Sept.)

Pregnant women are more prone to experience severe COVID-19 disease, including intensive care unit (ICU) admission, use of invasive ventilation, extracorporeal membrane oxygenation (ECMO), and mortality compared to non-pregnant individuals. Additionally, research suggests that SARS-CoV-2 infection during pregnancy is linked to adverse pregnancy outcomes, such as preterm birth, preeclampsia, and stillbirth, as well as adverse neonatal outcomes, including hospitalization and admission to the neonatal intensive care unit. This review assessed the available literature from November 2021 to 19 March 2023, concerning the safety and effectiveness of COVID-19 vaccination during pregnancy. COVID-19 vaccination administered during pregnancy is not linked to significant adverse events related to the vaccine or negative obstetric, fetal, or neonatal outcomes. Moreover, the vaccine has the same effectiveness in preventing severe COVID-19 disease in pregnant individuals as in the general population. Additionally, COVID-19 vaccination is the safest and most effective method for pregnant women to protect themselves and their newborns from severe COVID-19 disease, hospitalization, and ICU admission. Thus, vaccination should be recommended for pregnant patients. While the immunogenicity of vaccination in pregnancy appears to be similar to that in the general population, more research is needed to determine the optimal timing of vaccination during pregnancy for the benefit of the neonate

Julia-Burches C, Marinez-Varea A. J Personalized Med 2023;May

