COVID-19 HEALTH CARE PROVIDER UPDATE:

COVID-19 AND VACCINATION DURING PREGNANCY NEW YORK CITY COVID-19 UPDATES

OCTOBER 15, 2021

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Our understanding of COVID-19 is evolving rapidly. This presentation is based on our knowledge as of October10, 2021, 5 PM.

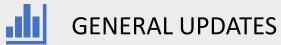












OUTLINE

GENERAL UPDATES

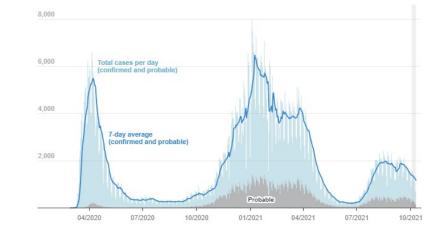
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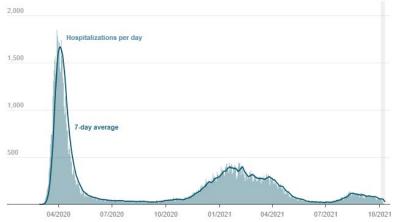


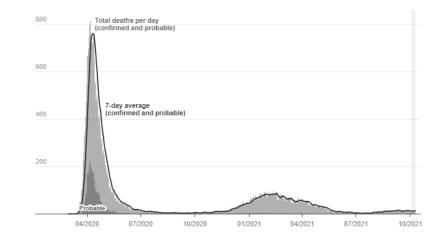
COVID-19, NYC, 3/1/2020-10/14/2021

Figures: Daily COVID-19 cases, hospitalizations, and deaths

NYC Health Department, COVID-19 data https://www1.nyc.gov/site/doh/covid/covid-19-data totals.page







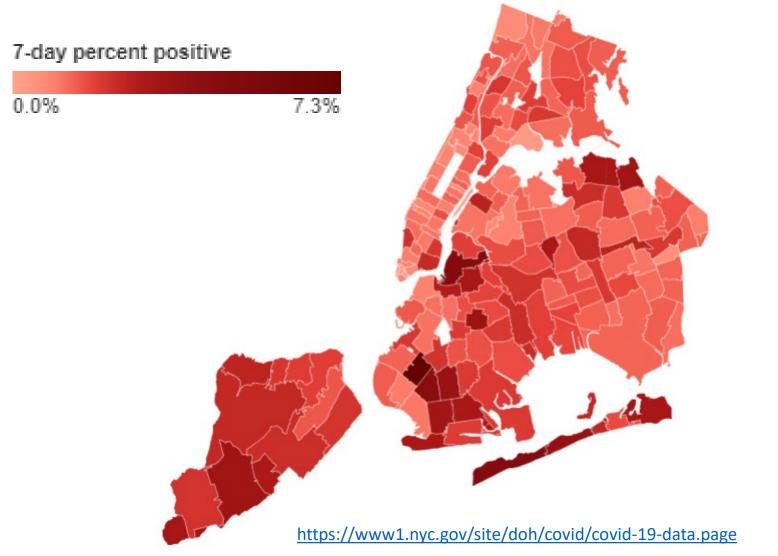


HOSPITALZATIONS

DEATHS

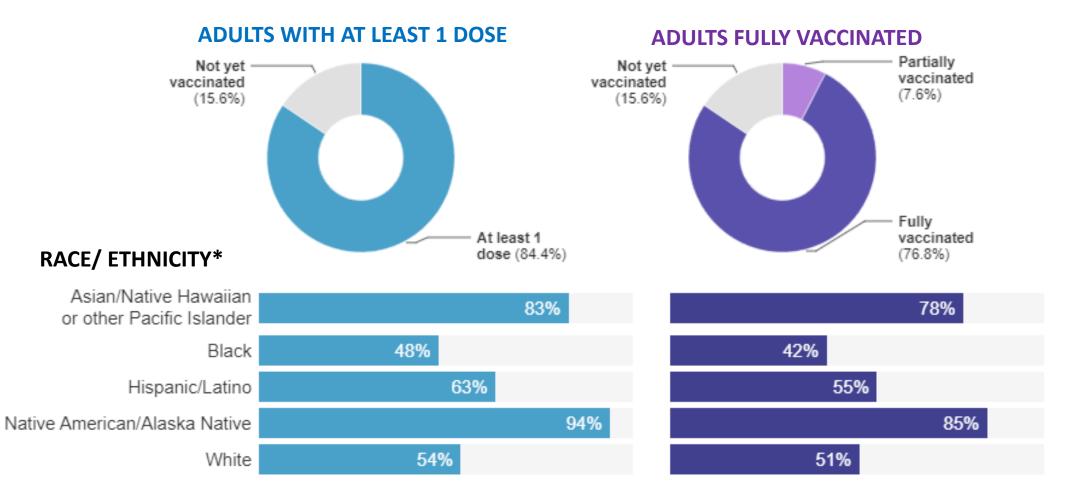
CASES

Recent Average Daily COVID-19 Percent Positive by NYC Zip Code





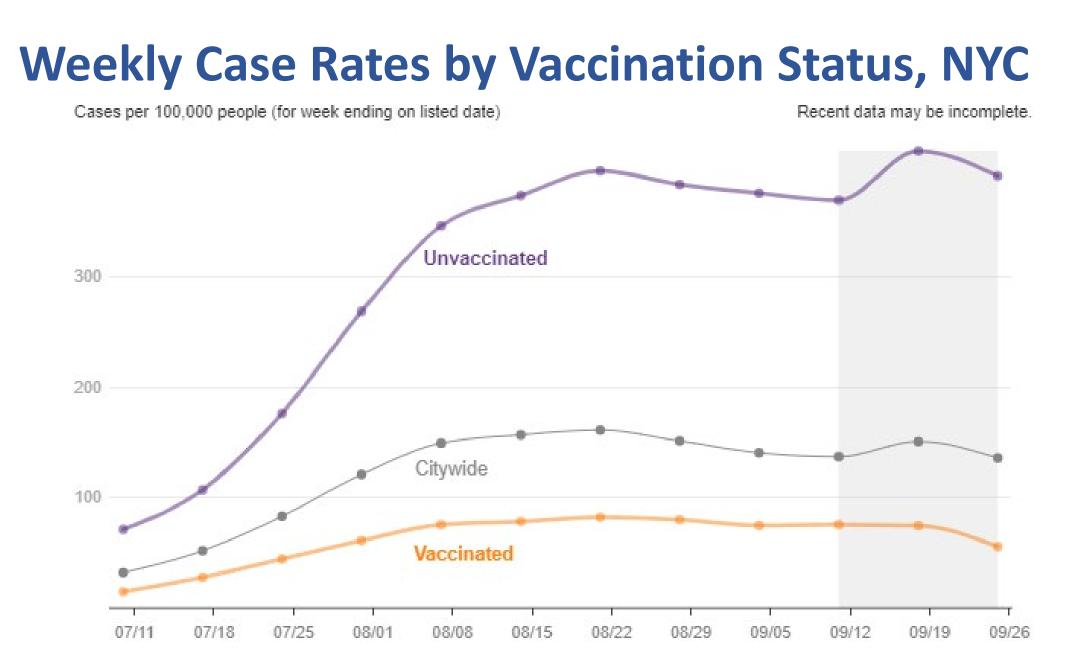
Percent of New Yorkers Vaccinated by Race/Ethnicity



https://www1.nyc.gov/site/doh/covid/covid-19-data-vaccines.page; updated 10/14/2021

* Race/ethnicity data includes all eligible New Yorkers





https://www1.nyc.gov/site/doh/covid/covid-19-data.page#daily on 10/14/21



Pfizer Booster Dose For Some Adults

- CDC recommends* a single Pfizer booster dose ≥ 6 months after completion of the primary Pfizer vaccine series for certain populations
- **Should** receive a booster:
 - People ages \geq 65 years
 - Residents ages \geq 18 years in long-term care facilities
 - People ages 50 64 years who have a medical condition that increases their risk for severe COVID-19 illness
- May receive a booster, based on individual benefits and risks:
 - People ages 18 49 years who have a medical condition that increases their risk for severe COVID-19 illness
 - People ages 18 64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting

*September 24, 2021: <u>https://www.cdc.gov/media/releases/2021/p0924-booster-recommendations-.html</u>



Benefits of Vaccination For People With History of COVID-19

- Among people with a history of COVID-19, vaccination:
 - Is associated with a decreased risk of reinfection
 - Observational study of people with prior SARS-CoV-2 infection found that unvaccinated people were more than twice as likely as fully vaccinated people to get reinfected¹
 - Can boost immune response for potentially more durable, longer-lasting protection
 - May offer better protection against COVID-19 variants
- People who have recovered from COVID-19 may be vaccinated as soon as they meet criteria to discontinue isolation

1. Cavanaugh AM, et al. Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination — Kentucky, May–June 2021. MMWR Morb Mortal Wkly Rep 2021;70:1081-1083. DOI: <u>http://dx.doi.org/10.15585/mmwr.mm7032e1</u>



Serologic Testing is Not Recommended For Vaccination Decisions

Serologic testing should **not** be used to determine if a person should receive COVID-19 vaccination

- Available antibody tests vary widely in performance, and none are approved to assess whether a person is protected against COVID-19
- Antibody levels may not correlate with immunity or clinical protection
- Neutralization tests used as surrogates of protection in scientific studies are not available for commercial use
- If someone misinterprets a positive antibody test, they may take fewer precautions, increasing their risk of being infected with and transmitting COVID-19

https://www1.nyc.gov/assets/doh/downloads/pdf/covid/providers/letter-to-providers-covid-19-vaccination-after-sars-cov-2-infection.pdf



Anticipated Developments in COVID-19 Vaccines

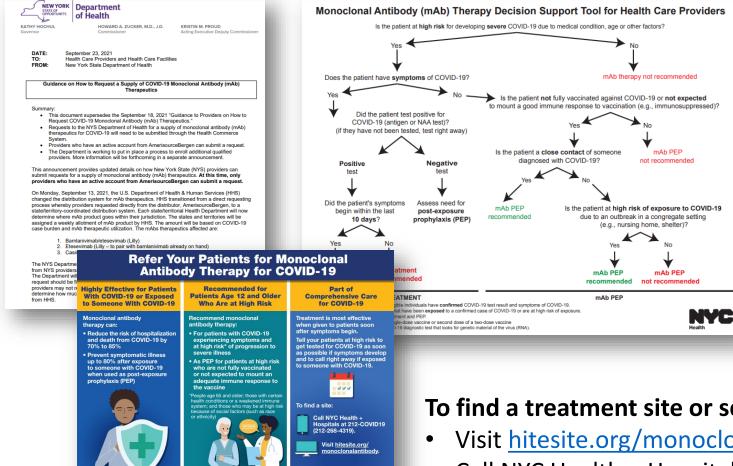
- FDA Vaccine Advisory group
 - Yesterday (October 14), recommended giving booster doses of Moderna's vaccine to same groups as for the Pfizer booster
 - The Moderna booster is 50-µg (half the dose used for the primary vaccine series)
 - Today will discuss and vote on whether to recommend giving booster doses of Johnson & Johnson vaccine, and will discuss mix-and-matching of different vaccines
 - ACIP scheduled to meet October 21, 2021
- Pfizer submitted data to support vaccination in 5 to 11-year-olds
 - FDA Advisory Committee meeting scheduled for October 26, 2021
 - ACIP scheduled to meet November 2-3, 2021
- Moderna has applied for full FDA approval for persons \geq 18 years
 - Approval may occur by the end of 2021



New Monoclonal Antibody Therapy Resources

PROVIDERS

https://www1.nyc.gov/site/doh/covid/covid-19-providers.page



NYC

PUBLIC

https://www1.nyc.gov/site/doh/covid/covid-19symptoms-chronic-health-risks.page **Exposed to or Positive for COVID-19? Ask Your Health Care Provider About Monoclonal Antibody Treatment** Monoclonal antibody treatment is for people who have COVID-19 or were recently exposed to someone who has COVID-19 Treatment Can reduce your risk of becoming sick from COVID-19 and help you avoid hospitalization Is recommended for anyone age 12 and older who is at high risk for severe COVID-19 illness, such as older adults; people with certain health conditions such as diabetes, obesity, or chronic kidney or lung disease; or people with a weakened immune system Early action is key. Treatment works best when you get it soon after COVID-19 symptoms begin, so it is important to get tested right away and ask your health care provider about treatment, including any possible side effects or treatment costs. To find a site offering treatme visit hitesite.org/monoclonalantibody 212-COVID19 (212-268-4319) to talk to visit **nyc.gov/vaccinefinder** or call

NYC

To find a treatment site or schedule an appointment

- Visit hitesite.org/monoclonalantibody OR
- Call NYC Health + Hospitals at 212-COVID19 (212-268-4319)

9.21



Update on COVID-19 infection, the vaccines, and pregnancy

Laura E. Riley, MD

Chair, Ob/Gyn at Weill Cornell Medicine and NewYork Presbyterian Hospital

October 15, 2021

Disclosures

- Writer for Up to Date
- Writer for Turner Publishing(You and Your Baby: pregnancy)
- Editorial board: New England Journal of Medicine and Contemporary Ob/gyn
- Medical Advisory Board: MAVEN, Parents Magazine

(CDC workgroup on COVID vaccines and VAst, ACOG Immunization Task Force and writer of ACOG practice advisory on COVID)



ACOG/SMFM/CDC recommendations:

- ACOG recommends that all eligible persons greater than age 12 years, including pregnant and lactating individuals, receive a COVID-19 vaccine or vaccine series.
- Document discussion of the vaccine. During subsequent office visits, address ongoing questions and concerns and offer vaccination again.
- Women's health care practitioners should lead by example by being vaccinated and encouraging eligible patients to be vaccinated as well.
- COVID-19 vaccines may be administered simultaneously with other vaccines such as influenza and Tdap.



ACOG/SMFM Recommendations:

- Moderately to severely immunocompromised people should receive a third dose of the Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines at least 28 days after the completion of the initial mRNA COVID-19 vaccine series.
- Individuals aged 18 through 64 years at high risk of severe COVID-19 are eligible for a COVID booster. Therefore, ACOG <u>recommends</u> that pregnant people, including pregnant health care workers, receive a booster dose of the Pfizer-BioNTech COVID-19 vaccine at least 6 months following the completion of their initial Pfizer-BioNTech COVID-19 vaccine series.
- People aged 18–64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting may receive a booster including HCW.



Characteristics of pregnant women admitted to hospital with confirmed SARS-CoV-2 infection in UK : (n=427 women)

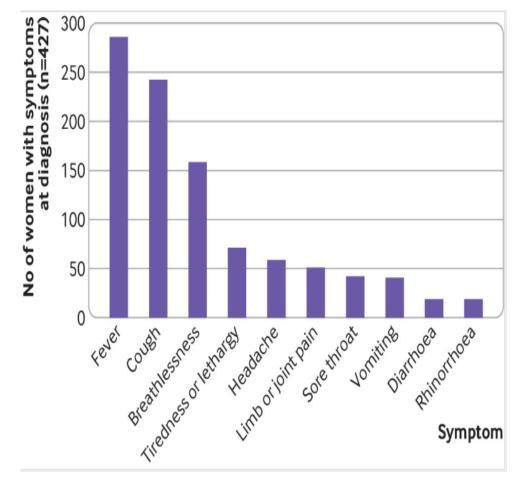


Table 2 Estimated incidence of admission with SARS-CoV-2 infection in pregnancy among different population subgroups

Characteristic	Estimated No of maternities	No of pregnant women admitted with SARS-CoV-2	Incidence per 1000 maternities	Rate ratio (95% Cl)
Age*, years:				
<20	2532	4	1.6	0.4 (0.1 to 1.1)
20-34	63 768	248	3.9	1 (reference)
≥35	19992	175	8.8	2.3 (1.8 to 2.7)
Body mass index†:				
Normal (<25)	36 377	126	3.5	1 (reference)
Overweight (25 to <30)	20 836	141	6.8	2.0 (1.5 to 2.5)
Obese (≥30)	16154	140	8.7	2.5 (2.0 to 3.2)
Ethnic group (England only)‡:				
White	49 282	173	3.5	1 (reference)
Asian	7400	103	13.9	4.0 (3.1 to 5.1)
Black	3135	89	28.4	8.1 (6.2 to 10.5)
Chinese/other	2960	28	9.5	2.7 (1.7 to 4.0)
Mixed	1304	9	6.9	2.0 (0.9 to 3.8)



Rates of Maternal and Perinatal Mortality and Vertical Transmission in Pregnancies complicated by SARS-CoV-2 Infection: a systematic review

- 13/99 articles includes 538 pregnancies w/confirmed SARS-CoV-2
- 435 (80.9 %) delivered
- Maternal ICU admission: 8/263 (3%)
- Maternal critical disease: 3/209 (1.4%)
- <u>No</u> maternal deaths
- C/S rate: 332/392 (84.7%)
- Preterm birth rate: 57/284 (20%)
- Vertical transmission: 0/310 (0%)



Characteristics of women of reproductive age with SARS CoV-2 (US Jan 22-Jul 7)

- 300,000+ SARS-CoV-2-positive reproductive age women
- 8,207 pregnant (9.0%)
- CVD, DM & chronic lung disease: more frequent among pregnant women
- Increased risk of hospitalization: aRR 5.4 (5.1-5.6)
- Increased risk of ICU admission: aRR 1.5 (1.2-1.8)
- Increased risk of mechanical ventilation: aRR 1.7 (1.2-2.4)
- No differences in death: aRR 0.9 (0.5-1.5)



Additional observations:

•Khoury et al: 5 NYC hospitals, 241 COVID+ pregnant women

- 102 (42.3%) asymptomatic
- 64 (26.5%) mild, 63 (26.1%) severe, 12 (5.0%) critical
- COVID severity associated with higher BMI and increased CD rates

•Emeruwa et al: COVID transmission associated with neighborhood markers of household crowding and low SES

•Goldfarb et al: 65 Hispanic and 127 non-Hispanic women with sx of COVID 19 (71% tested) 72% Hispanic women vs 27% non-Hispanic women were positive p<.001.



Clinical manifestations, risk factors & maternal and perinatal outcomes: living systematic review and meta-analysis (Dec 2019-June 2020)

- 77 Studies including 13,118 pregnant women and 83,486 nonpregnant women
- Risk factors for COVID: advanced maternal age, higher BMI, chronic hypertension, preexisting diabetes
- Maternal co-morbidities: risk factors for ICU admission and invasive ventilation
- Maternal outcomes: all cause mortality (.006), ICU admission(.03), Invasive ventilation (.01)
- Fetal/neonatal outcomes: preterm birth, stillbirth, cesarean delivery, NICU admission



Additional pregnancy observations

In an adjusted analysis of 1,219 pregnant women:

- Severe-critical COVID-19 vs mild disease
- Cesarean delivery: 59.6% vs 34%, aRR 1.57 (1.30-1.90)
- Hypertensive disorders: 40.4% vs18.9%, aRR 1.61 (1.18-2.20)



Khoury et al Obstet Gynecol 2020; Metz et al Obstet Gynecol 2021 Birth and Infant Outcomes after COVID Infection in pregnancy

- Among 3912 infants with known gestational age born to women with documented SARS-CoV-2 infection
- 12.9% were preterm (<37 weeks)
- Among 610 (21.3%) infants with test results: 2.6% had positive SARS-CoV-2



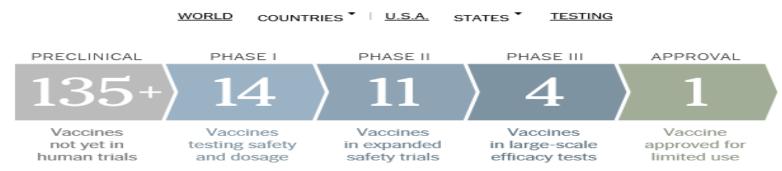
Data on COVID-19 during Pregnancy: Birth and Infant Outcomes

Data Reported to CDC as of September 3, 2021

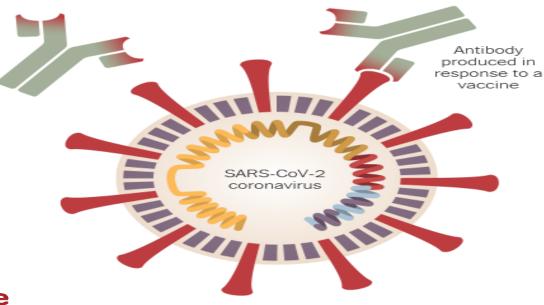


Coronavirus Vaccine Tracker

By Jonathan Corum, Denise Grady, Sui-Lee Wee and Carl Zimmer Updated July 11, 2020

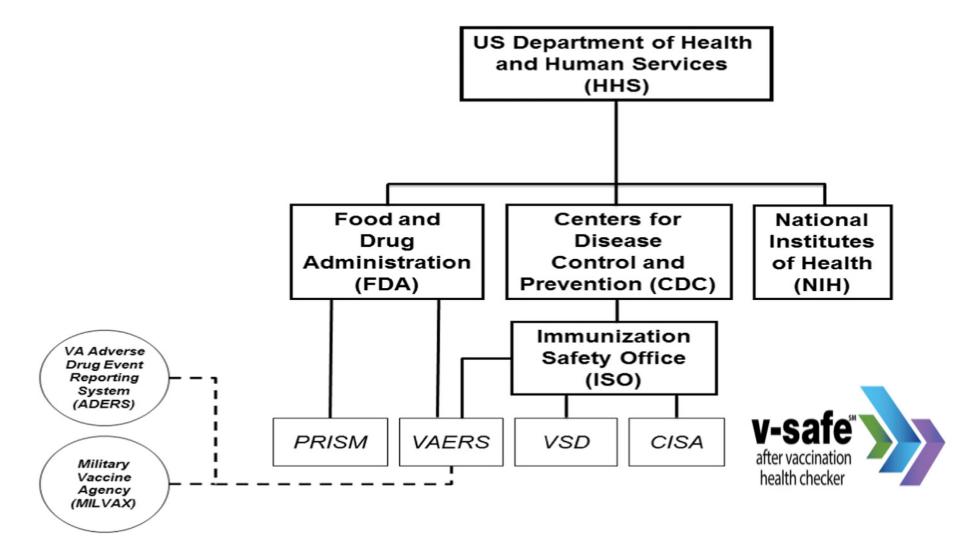


Researchers around the world are developing <u>more than 155</u> <u>vaccines</u> against the coronavirus, and **22 vaccines** are in human trials. Vaccines typically require years of research and testing before reaching the clinic, but scientists are racing to produce a <u>safe and effective vaccine</u> by next year.





Vaccine Monitoring System







Active safety monitoring for COVID-19 vaccines

- V-safe is a new CDC smart-phone based monitoring program for COVID-19 vaccine safety
 - uses text messaging and web surveys to check-in with vaccine recipients after vaccination
 - participants can report side effects and health impact events after COVID-19 vaccination
 - includes active telephone follow-up by CDC for reports of significant health impact
 - captures information on pregnancy status and enables follow-up on pregnant women







V-safe and Registry Monitoring People Who Report Pregnancy

v-safe After Vaccination Health Checker Pregnant people reported, United States, as of October 4, 2021

163,777

v-safe COVID-19 Vaccine Pregnancy Registry Pregnant people enrolled, United States, as of October 4, 2021

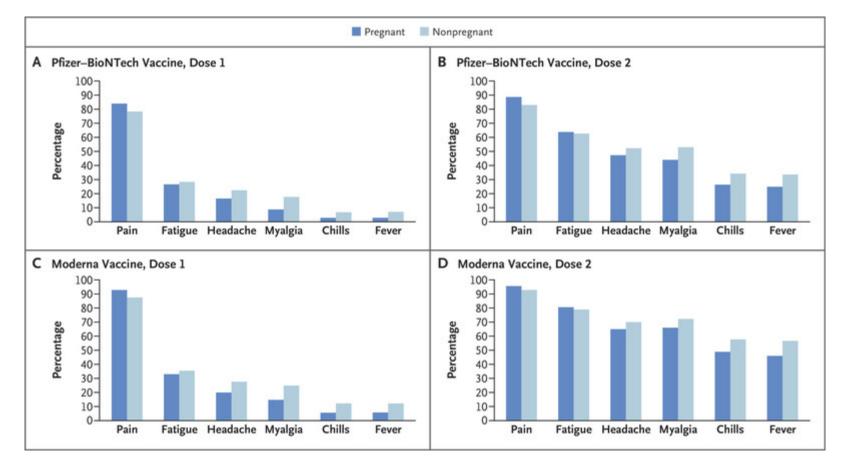
5,104

As of October 4, 2021, more than 163 thousand **v-safe** participants have indicated they were pregnant at the time they received COVID-19 vaccination. CDC is currently enrolling eligible participants and analyzing data to better understand how COVID-19 vaccination affects pregnant people. As CDC learns more about the effects of vaccination during pregnancy, data will be presented at the Advisory Committee on Immunization Practices (ACIP) meetings, which are open to the public, and in published reports.



Preliminary findings of mRNA COVID vaccine safety

Figure 1. Most Frequent Local and Systemic Reactions Reported in the V-safe Surveillance System on the Day after mRNA Covid-19 Vaccination.



Weill Cornell Medicine
Obstetrics & Gynecology

Preliminary findings of mRNA COVID vaccine safety

Neonatal outcome among live-born infants		
Preterm birth: <37 wk ^{21,22}	8–15	60/636 (9.4)¶
Small size for gestational age ^{23,24}	3.5	23/724 (3.2)
Congenital anomalies ²⁵ **	3	16/724 (2.2)
Neonatal death ²⁶ ††	<1	0/724

* The populations from which these rates are derived are not matched to the current study population for age, race and ethnic group, or other demographic and clinical factors.

- † Data on pregnancy loss are based on 827 participants in the v-safe pregnancy registry who received an mRNA Covid-19 vaccine (BNT162b2 [Pfizer-BioNTech] or mRNA-1273 [Moderna]) from December 14, 2020, to February 28, 2021, and who reported a completed pregnancy. A total of 700 participants (84.6%) received their first eligible dose in the third trimester. Data on neonatal outcomes are based on 724 live-born infants, including 12 sets of multiples.
- ‡ A total of 96 of 104 spontaneous abortions (92.3%) occurred before 13 weeks of gestation. No denominator was available to calculate a risk estimate for spontaneous abortions, because at the time of this report, follow-up through 20 weeks was not yet available for 905 of the 1224 participants vaccinated within 30 days before the first day of the last menstrual period or in the first trimester. Furthermore, any risk estimate would need to account for gestational week–specific risk of spontaneous abortion.
- § The denominator includes live-born infants and stillbirths.
- The denominator includes only participants vaccinated before 37 weeks of gestation.
- Small size for gestational age indicates a birthweight below the 10th percentile for gestational age and infant sex according to INTERGROWTH-21st growth standards (http://intergrowth21.ndog.ox.ac.uk). These standards draw from an international sample including both low-income and high-income countries but exclude children with coexisting conditions and malnutrition. They can be used as a standard for healthy children growing under optimal conditions.
- ** Values include only major congenital anomalies in accordance with the Metropolitan Atlanta Congenital Defects Program 6-Digit Code Defect List (www.cdc.gov/ncbddd/birthdefects/macdp.html); all pregnancies with major congenital anomalies were exposed to Covid-19 vaccines only in the third trimester of pregnancy (i.e., well after the period of organogenesis).
- †† Neonatal death indicates death within the first 28 days after delivery.



Shimabukuro TT, et al. N Engl J Med. 2021 Apr 21

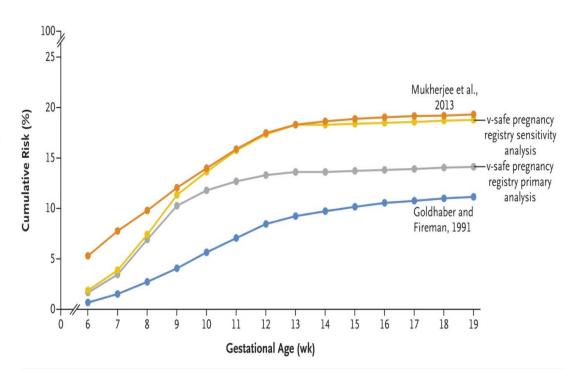
mRNA vaccines not associated with SAb

Research letter based on VSD

Table 2. Adjusted Odds Ratios for Receipt of COVID-19 Vaccine Within 28 Days Prior to a Spontaneous Abortion, December 15, 2020, Through June 28, 2021, Across 8 Vaccine Safety Datalink Sites and Among 264 104 Pregnancy-Periods^a

	Adjusted odds ratio (95% CI) ^b
Full population	1.02 (0.96-1.08)
By gestational age, wk	
6-8	0.94 (0.86-1.03)
9-13	1.07 (0.99-1.17)
14-19	1.08 (0.89-1.29)
By vaccine type ^c	
mRNA-1273 (Moderna)	1.03 (0.94-1.11)
BNT162b2 (Pfizer-BioNTech)	1.03 (0.95-1.11)

Research letter based on V-safe



Maternal COVID vaccine antibodies and neonatal cord blood

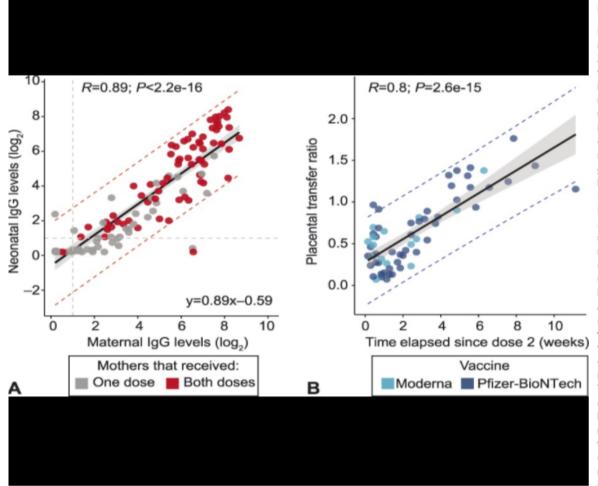


Fig. 2.

Neonatal antibody response to maternal coronavirus disease 2019 (COVID-19) mRNA vaccination. A. Cord blood immunoglobulin (Ig)G levels vs maternal IgG levels. Grey dots represent neonates born to mothers who received only one dose of the vaccine. All positive serology cutoffs were 1 (dashed grey line). The relationship between maternal and neonatal IgG levels was studied using Pearson correlation analysis and linear regression on log2scaled serologic values. Cls are represented by shaded region (95% CI 0.80-0.97). Lower and upper prediction intervals are indicated with dotted red lines.B. Placental transfer ratio (neonatal IgG/maternal IgG) vs weeks elapsed since maternal vaccination dose 2 for 65 dyads containing mothers who received both vaccine doses. Time point 0 is day of vaccine dose 2. The relationship between IgG placental transfer ratio (neonatal/maternal) and time was studied using Pearson correlation analysis and linear regression on placental transfer ratio and time plancod cinco

Weill Cornell Medicine Obstetrics & Gynecology

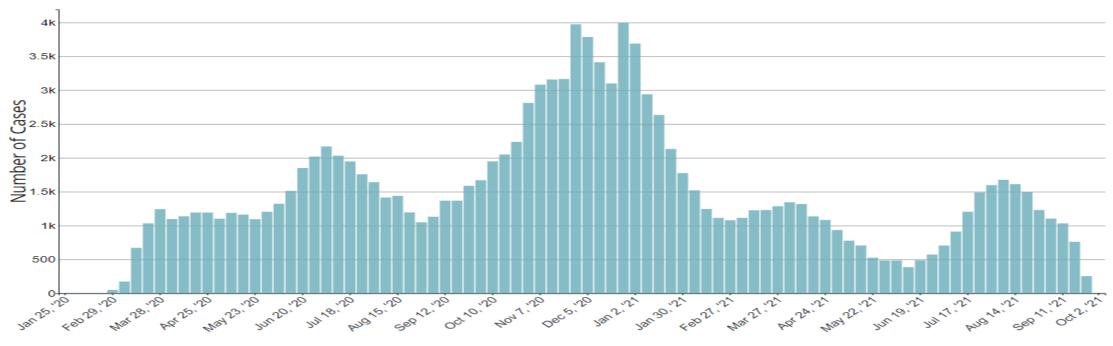
Prabhu et al. Obstetrics & Gynecology: April 28, 2021

Pregnancy enhanced surveillance

Pregnant women¹ with COVID-19, United States, January 22, 2020 - October 4, 2021

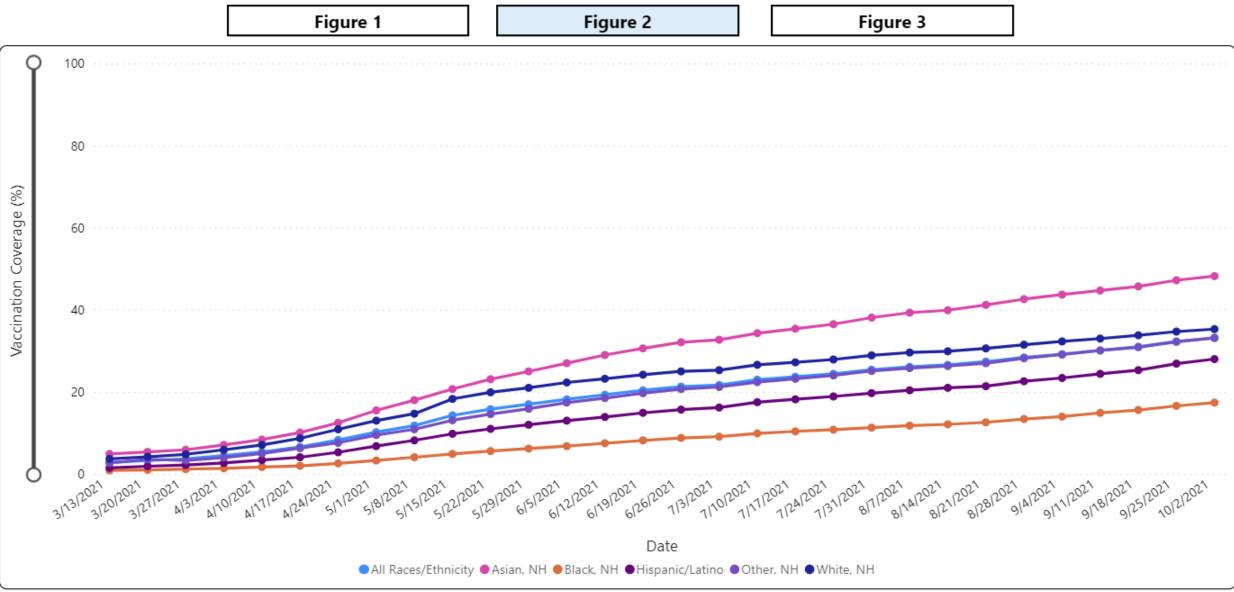


Cases of COVID-19 among Pregnant Women by Week of Diagnosis* Data were collected from 127,193 women and date of diagnosis** was available for 127,193 (100%) women.



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

Figure 2: Percent of Pregnant People Aged 18–49 Years Fully Vaccinated with COVID-19 Vaccine Prior to or during Pregnancy Overall, by Race/Ethnicity, and Date Reported to CDC – Vaccine Safety Datalink*, United States December 14, 2020 – October 2, 2021



NH = Non-Hispanic; "Other, NH" race includes American Indian or Alaska Native, Native Hawaiian or Pacific Islander, and Multiple or Other races; "vaccination coverage" represents the total number of pregnant people (denominator as of October 2, 2021 = 195,089) who were fully vaccinated, including both doses of the Pfizer-BioNTech or Moderna vaccines or a single dose of the Johnson's Janssen vaccine.

COVID Vaccines and Infertility

Does mRNA SARS-CoV-2 vaccine influence patients' performance during IVF-ET cycle?

36 couples resumed IVF 7-85d post vaccine

No in between cycle differences in ovarian stimulation and embryological variables before & after vaccine

mRNA vaccine did not affect pts' performance or ovarian reserve in subsequent IVF cycle SARS-CoV-2 spike protein seropositivity from vaccination or infection does not cause sterility

- 171 frozen embryo transfers performed and compared between SARS-CoV-2 vaccine positive, infection positive and seronegative women
- No difference in serum hCG documented implantation rates or sustained implantation rates between 3 groups

Selected references

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- Morris, R. S., SARS-CoV-2 spike protein seropositivity from vaccination or infection does not cause sterility. Fertil Steril Rep 2021 2666-3341



- COVID infection in pregnancy is associated with severe morbidity and mortality.
- COVID cases in pregnancy occur even in "healthy" people.
- Current data show that most hospitalized pregnant people are unvaccinated and only about 30% of pregnant women are vaccinated.
- COVID vaccines are safe during all trimesters of pregnancy including preconception.
- COVID vaccines are not associated with infertility.
- Studies of covid vaccines and menstrual irregularities are underway but preliminary observations suggest that the changes are transient.

Additional COVID-19 Resources

COVID-19 Vaccines

- NYC Health Department COVID-19 Vaccine:
 - Providers:
 - Vaccine information: <u>nyc.gov/health/covidvaccineprovider</u>
 - Provider hotline to schedule vaccine appointments: 877-VAX-4NYC (877-8229-4692); press 2 at second prompt
 - Public: <u>nyc.gov/covidvaccine</u>
- Citywide Immunization Registry Reporting Assistance
 - <u>https://www1.nyc.gov/site/doh/providers/reporting-and-services/cir-how-to-report.page#electronic</u>
- Vaccine Provider Assistance: <u>nycimmunize@health.nyc.gov</u>

General COVID-19 Resources

- Provider page: <u>https://www1.nyc.gov/site/doh/covid/covid-19-providers.page</u>
- Data page: <u>https://www1.nyc.gov/site/doh/covid/covid-19-data.page</u>
- Dear Colleague COVID-19 newsletters (sign up for City Health Information subscription at: nyc.gov/health/register)
- NYC Health Alert Network (sign up at <u>https://www1.nyc.gov/site/doh/providers/resources/health-alert-network.page</u>)
- Provider Access Line: 866-692-3641



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